No. 95-754-CFX
Status: GRANTED

Title: Medtronic, Inc., Petitioner
v.
Lora Lohr, et vir

Docketed:
November 14, 1995

Court: United States Court of Appeals for the Eleventh Circuit

Vide:
95-886

Counsel for petitioner: Jarcho,Daniel Gordon

Counsel for respondent: Wolfman,Brian

Entry	Date	Note	Proceedings and Orders
1	Nov 13 1995	G	Petition for writ of certiorari filed. (Response due December 14, 1995)
2	Dec 6 1995		Brief of respondents Lora Lohr, et vir in opposition filed.
3	Dec 27 1995		DISTRIBUTED. January 12, 1996 (Page 4)
5	Jan 16 1996		REDISTRIBUTED. January 19, 1996 (Page 13)
6	Jan 19 1996		Petition GRANTED. The briefs of petitioners are to be filed with the Clerk and served upon opposing counsel on or before 3 p.m., Friday, March 1, 1996. The briefs of respondents are to be filed with the Clerk and served upon opposing counsel on or before 3 p.m., Friday, March 29, 1996. A reply brief, if any, is to be filed pursuant to Rule 25.3. Rule 29.2 does not apply. **********
7	Feb 5 1996		AMICUS CURIAE BRIEFS SHALL BE RECEIVED NO LATER THAN 4:00 P.M., MARCH 13, 1996.
8	Feb 7 1996	G	Motion of petitioner Medtronic, Inc. to dispense with printing the joint appendix filed.
10	Feb 16 1996		SET FOR ARGUMENT TUESDAY, APRIL 23, 1996. (1ST CASE).
9	Feb 20 1996		Motion of petitioner Medtronic, Inc. to dispense with printing the joint appendix GRANTED.
11	Mar 1 1996		Brief of petitioner Medtronic, Inc. filed. VIDED.
12	Mar 1 1996		Brief of cross-petitioners Lora Lohr and Michael Lohr filed. VIDED.
13	Mar 8 1996		CIRCULATED.
29	Mar 11 1996	X	Brief amici curiae of Two Products Liability Law Professors, Pearson and Noah filed. VIDED.
17	Mar 12 1996	X	Brief amici curiae of Florida, et al. filed.
19	Mar 12 1996	X	Brief amicus curiae of Plaintiffs' Legal Committee in MDL Docket No. 1014 filed. VIDED.
22	Mar 12 1996	X	Brief amicus curiae of Product Liability Advisory Council, Inc. filed. VIDED.
14	Mar 13 1996	X	Brief amicus curiae of General Motors Cororation filed. VIDED.
15	Mar 13 1996		Brief amici curiae of Center for Patient Advocacy, et al. filed. VIDED.
16	Mar 13 1996	X	Brief amicus curiae of Trial Lawyers for Public Justice filed. VIDED.
18	Mar 13 1996	X	Brief amici curiae of American Association of Retired Persons, et al. filed. VIDED.
20	Mar 13 1996	X	Brief amicus curiae of Washington Legal Foundation filed. VIDED.
21	Mar 13 1996	X	Brief amicus curiae of Collagen Corporation filed. VIDED.

No. 95-754-CFX

Entry	Date	Note	Proceedings and Orders
23	Mar 13 1996	X	Brief amicus curiae of Medical Device Manufacturers Association filed. VIDED.
24	Mar 13 1996	X	Brief amici curiae of American Insurance Association, et al. filed. VIDED.
25	Mar 13 1996	X	Brief amici curiae of National Conference of State Legislatures, et al. filed. VIDED.
26	Mar 13 1996	X	Brief amici curiae of Health Industry Manufacturers, et al. filed. VIDED.
27	Mar 13 1996	X	Brief amicus curiae of California filed. VIDED.
28	Mar 13 1996	X	Brief amicus curiae of United States filed. VIDED.
30	Mar 25 1996	G	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
32	Mar 29 1996	X	Brief of respondents Lora and Michael Lohr filed. VIDED.
33	Mar 29 1996	X	Brief of Cross-Respondent Medtronic, Inc. filed. VIDED.
34	Mar 29 1996		LODGING consisting of ten copies of article "Preemption and Medical Devices: A Response to Adler and Mann", submitted by counsel for Medtronic, Inc.
31	Apr 1 1996		Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
35	Apr 1 1996		Record filed.
		*	Original record proceedings U.S.Court of Appeals,Eleventh Circuit; U.S.District Court,Middle Dist.Florida (BOX)
36	Apr 16 1996	X	Reply brief of petitioners Lora Lohr and Michael Lohr filed. VIDED.
37	Apr 16 1996	X	Reply brief of petitioner Medtronic, Inc. filed. VIDED.
38	Apr 23 1996		ARGUED.

Supreme Court, U.S.
FILED

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No. 95-

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

RULE 29.6 STATEMENT

Petitioner Medtronic, Inc. has no parent corporation and has no nonwholly owned subsidiaries.

TABLE OF CONTENTS

QUESTIONS PRESENTED i
RULE 29.6 STATEMENT ii
TABLE OF AUTHORITIES v
OPINIONS BELOW 1
JURISDICTION 2
STATUTORY AND REGULATORY PROVISIONS INVOLVED 2
STATEMENT OF THE CASE 2
A. Background and Significance of the Federal Law Question 2
B. This Litigation 7
C. The Court of Appeals Opinion 8
REASONS FOR GRANTING THE WRIT 11
I. THE COURT OF APPEALS DECISION ESTABLISHES A DIRECT CONFLICT WITH DECISIONS OF OTHER COURTS OF APPEALS 11
II. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT 18
CONCLUSION 21
APPENDIX A (*Lohr v. Medtronic, Inc.*, No. 94-2516 (11th Cir. July 3, 1995)) 1a

APPENDIX B (*Lohr v. Medtronic, Inc.*, No. 93-482-Civ-J-20 (M.D. Fla. Mar. 16, 1994)) (order) 1b

APPENDIX C (*Lohr v. Medtronic, Inc.*, No. 93-482-Civ-J-20 (M.D. Fla. Feb. 16, 1994)) (order) 1c

APPENDIX D (*Lohr v. Medtronic, Inc.*, No. 93-482-Civ-J-20 (M.D. Fla. Dec. 17, 1993)) (order) 1d

APPENDIX E (*Lohr v. Medtronic, Inc.*, No. 94-2516 (11th Cir. Aug. 15, 1995)) (denying petition for rehearing and suggestion of rehearing en banc) 1e

APPENDIX F (setting forth verbatim the following statutory and regulatory provisions: 21 U.S.C. §§ 360(k), 360k (1994); 21 C.F.R. §§ 807.81(a)(3), 807.87, 808.1(d) (excerpt), 870.3680(b), (c) (1995)) 1f

TABLE OF AUTHORITIES

CASES

Anguiano v. E.I. du Pont de Nemours & Co., 44 F.3d 806 (9th Cir. 1995) 17

Becker v. Optical Radiation Corp., 66 F.3d 18 (2d Cir. 1995) 15

Bokis v. American Medical Systems, Inc., 875 F. Supp. 748 (W.D. Okla. 1995) 13

Bollier v. Medtronic, Inc., No. H-92-2439, 1993 WL 734843 (S.D. Tex. Oct. 28, 1993) 13

Caraballo v. Intermedics, Inc., 886 F. Supp. 974 (D.P.R. 1995) 13

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 8

Duncan v. Iolab Corp., 12 F.3d 194 (11th Cir. 1994) 7,17

Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995) 11,12,19,20

English v. Mentor Corp., No. 94-1714, 1995 U.S. App. LEXIS 27670 (3d Cir. Sept. 29, 1995), *aff'g in part, rev'g in part* No. 93-2725, 1994 U.S. Dist. LEXIS 7941 (E.D. Pa. June 10, 1994) 12,19,20

Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995) 12,13,19,20

Fender v. Medtronic, Inc., 887 F. Supp. 1326 (E.D. Cal. 1995) 13

Fogal v. Steinfeld, 620 N.Y.S.2d 875 (N.Y. Sup. Ct. 1994) 13

Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994) 17

Jacobs v. E.I. du Pont de Nemours & Co., No. 93-4144, 1995 U.S. App. LEXIS 29436 (6th Cir. Oct. 19, 1995) 17

Kennedy v. Collagen Corp., No. 94-15197, 1995 WL 606511 (9th Cir. Oct. 17, 1995) 16

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) 14

LaMontagne v. E.I. du Pont de Nemours & Co., 41 F.3d 846 (2d Cir. 1994), *aff'g* 834 F. Supp. 576 (D. Conn. 1993) 17

Larsen v. Pacesetter Systems, Inc., 837 P.2d 1273 (Haw. 1992) 13

Martello v. Ciba Vision Corp., 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995) 14

Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994) 17,19

Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995) 17

Mitchell v. Collagen Corp., No. 94-3946, 1995 U.S. App. LEXIS 27709 (7th Cir. Oct. 2, 1995) 14

Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989) 17

National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) 14

Reeves v. AcroMed Corp., 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995) 17

Slater v. Optical Radiation Corp., 961 F.3d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992) 15

Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993) 17

Sylvester v. Mentor Corp., No. 95-67, 1995 La. App. LEXIS 2490 (La. Ct. App. Sept. 20, 1995) 13

Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995) 17

STATUTES

Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-395 (1994) 1

21 U.S.C. § 360(k) 2,6

21 U.S.C. § 360c(a)(1)(A) 4

21 U.S.C. § 360c(a)(1)(B) 4

21 U.S.C. § 360c(a)(1)(C) 5,18

21 U.S.C. § 360c(b)(1) 4

21 U.S.C. § 360e(a)(1) 5,16

21 U.S.C. § 360e(c) 5

21 U.S.C. § 360e(d) 5

21 U.S.C. § 360e(d)(1)(A) 15

21 U.S.C. § 360j(g) 5

21 U.S.C. § 360k 2

21 U.S.C. § 360k(a) 4,8,10

21 U.S.C. § 360k(b) 4

28 U.S.C. § 1254(1) (1988) 2
28 U.S.C. § 1332(a) (1988) 7
28 U.S,C. § 1441 (1988 & Supp. V 1993) 7

REGULATIONS

21 C.F.R. § 801.109 (1995) 9
21 C.F.R. § 807.81(a)(3) (1995) 2,16
21 C.F.R. § 807.81(a)(3)(i) 6,15
21 C.F.R. § 807.87 (1995) 2,6,15
21 C.F.R. § 807.100 (1995) 15
21 C.F.R. § 808.1(d) (1995) 2,8,16
21 C.F.R. § 812.20 (1995) 15
21 C.F.R. § 812.25 (1995) 15
21 C.F.R. § 812.30 (1995) 15
21 C.F.R. § 812.30(b)(1) 15
21 C.F.R. § 812.35(a)(1) (1995) 15
21 C.F.R. § 813.20 (1995) 15
21 C.F.R. § 813.25 (1995) 15
21 C.F.R. § 813.35(a)(9) (1995) 15
21 C.F.R. § 813.39(b)(1) (1995) 15
21 C.F.R. § 814.20 (1995) 15
21 C.F.R. § 814.39(a) (1995) 15
21 C.F.R. pt. 820 (1995) 10
21 C.F.R. § 860.84 (1995) 4
21 C.F.R. § 860.95(a) (1995) 6

21 C.F.R. § 870.3680(b) (1995) 2,7
21 C.F.R. § 870.3680(c) (1995) 2,7
21 C.F.R. § 876.5860 (1995) 18
21 C.F.R. § 878.3530 (1995) 18
21 C.F.R. § 888.3330 (1995) 18

OTHER AUTHORITIES

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) 3,4,6
H.R. Rep. No. 808, 101st Cong., 2d Sess., *reprinted in* 1990 U.S.C.C.A.N. 6305 3,6,18
S. Rep. No. 33, 94th Cong., 2d Sess., *reprinted in* 1976 U.S.C.C.A.N. 1070 3
Petition for Certiorari, *Shiley, Inc. v. Michael*, No. 94-1971, *cert. denied*, 116 S. Ct. 67 (Oct. 2, 1995) 19

No. 95-

IN THE
SUPREME COURT OF THE UNITED STATES
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MEDTRONIC, INC.,
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Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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PETITION FOR WRIT OF CERTIORARI

Petitioner Medtronic, Inc. hereby petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case. The Eleventh Circuit held that state common law claims alleging defects in the design of a medical device were not preempted, even though those claims would establish state law design requirements different from, and in addition to, design requirements imposed under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-395 (1994).

OPINIONS BELOW

The opinion of the court of appeals (App. 1a) is reported at 56 F.3d 1335 (11th Cir. 1995). The opinion of the United States District Court for the Middle District of Florida

granting summary judgment against respondents (App. 1b) is not reported.

JURISDICTION

The court of appeals entered judgment on July 3, 1995. Medtronic filed a timely petition for rehearing and suggestion of rehearing in banc on July 24, 1995, which the court of appeals denied on August 15, 1995. This Court has jurisdiction under 28 U.S.C. § 1254(1) (1988).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The appendix (App. 1f) sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. §§ 360(k), 360k (1994); 21 C.F.R. §§ 807.81(a)(3), 807.87, 808.1(d) (excerpt), 870.3680(b), (c) (1995).

STATEMENT OF THE CASE

In direct conflict with two other circuits, the Eleventh Circuit held that the FDCA does not preempt state common law claims arising from a medical device's design, even though the federal Food and Drug Administration had reviewed and affirmatively authorized that design for marketing pursuant to the FDCA. This petition asks this Court to review a question of profound significance to all manufacturers and users of rapidly advancing medical device technology—whether manufacturers may be held liable under state law for alleged defects in a medical device design authorized by federal law.

A. Background and Significance of the Federal Law Question

In 1976, Congress passed the Medical Device Amendments to the FDCA, establishing comprehensive federal regulation of medical devices for the first time. Under the Medical Device Amendments, the United States Food and Drug Administration ("FDA") has extensive authority to ensure the safety and effectiveness of medical devices. Congress enacted the Medical Device Amendments as "a balanced regulatory proposal" intended to assure both that the public's health is protected and that "innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Through the Medical Device Amendments, Congress sought to encourage research and development of "sophisticated, critically important medical devices," as well as to give the FDA the necessary authority to ensure the public's health and safety. S. Rep. No. 33, 94th Cong., 2d Sess. 2, *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. The technological innovations spawned under this regulatory scheme have been substantial; in 1990, Congress estimated that 5,000 new medical devices enter the market each year under the FDA's authority. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307.

Consistent with the congressional intent to promote innovation by eliminating unnecessary regulation, the Medical Device Amendments include the following express preemption provision:

> Except as provided in subsection (b) . . . no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1994).[1] The House committee report for the Medical Device Amendments describes the preemption provision as a "general prohibition on non-Federal regulation," making clear that Congress intended broad preemption of state law under section 360k. H.R. Rep. No. 853, at 45.

The federal requirements giving rise to preemption under section 360k are extensive. Under the FDCA, the FDA regulates medical devices in the context of a classification scheme that distinguishes among devices based upon the concerns they raise about safety and effectiveness. The FDA assigns medical devices intended for human use to one of three classes, effectuating its classification decision through notice and comment rulemaking procedures. *See* 21 U.S.C. § 360c(b)(1) (1994); 21 C.F.R. § 860.84 (1995). Class I devices, which the FDA believes pose no unreasonable health risks, are subject to general controls designed to ensure that labeling is accurate and the product is safe when used as directed. *See* 21 U.S.C. § 360c(a)(1)(A) (1994). Class II devices are those for which special controls may be necessary to assure safety and effectiveness. *Id.* § 360c(a)(1)(B). These special controls may include performance standards, postmarket surveillance, patient registries, and other requirements the FDA deems appropriate. *Id.* The present case involves a Class III device. In general, Class III devices are

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[1] The exception in subsection (b) permits states to apply for an exemption from the preemption imposed by subsection (a). *Id.* § 360k(b).

those represented to be life-sustaining or life-supporting, or those presenting a potentially unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C).

The regulatory structure established by the Medical Device Amendments requires the FDA to review and authorize distribution of new medical devices. The FDA conducts this review under one of three clearance processes. First, the FDA regulates clinical experimentation with new devices through the investigational device exemption ("IDE") process. In order to obtain FDA approval for a clinical experiment, the sponsor must submit an IDE application containing significant information about the device and a proposed experimental plan. The FDA then reviews and, if appropriate, approves the application, which authorizes distribution of the device solely for experimental use. *See id.* § 360j(g).

Second, through the premarket approval process, the FDA authorizes marketing of some Class III devices to the general public. To obtain this authorization, the manufacturer submits a premarket approval application ("PMA") containing significant information about the device for FDA review. If clinical data and other information in the PMA demonstrate that the device's safety and effectiveness are reasonably assured, the FDA approves marketing. *See id.* § 360e(c), (d). As the court of appeals below explained, the premarket approval process involves the most stringent regulatory review undertaken by the FDA. *See* App. 4a.

A third clearance process applies to other Class III devices, such as the one at issue in this case, for which no PMA is required until specifically called for by regulation. *See* 21 U.S.C. § 360e(a)(1) (1994). Until the FDA decides that PMAs are necessary, these Class III devices are subject to FDA premarket clearance through the "510(k)" process be-

fore they may be marketed legally under the FDCA. This process is established by, and named after, section 510(k) of the FDCA, 21 U.S.C. § 360(k). Through the 510(k) process, FDA determines whether devices are substantially equivalent to "preamendment" devices marketed prior to the adoption of the Medical Device Amendments in 1976. The 510(k) substantial equivalence determination is designed to ensure that new devices are as safe and effective as preamendment devices. *See* H.R. Rep. No. 853, at 36-37 (explaining that substantial equivalence determination involves safety and effectiveness determination). Because Class II and some Class I devices also enter the market through the 510(k) process, *cf.* 21 C.F.R. § 860.95(a) (1995), the FDA subjects a substantial number of devices to 510(k) review. Congress noted in 1990 that "98 percent of the estimated 5,000 devices that enter the market every year" do so through the 510(k) process. H.R. Rep. No. 808, at 14, *reprinted in* 1990 U.S.C.C.A.N. 6307.

Under the 510(k) process, Class III device manufacturers such as Medtronic must submit significant information—including design information—proving substantial equivalence before the FDA will authorize marketing. *See* 21 C.F.R. § 807.87. The 510(k) process also imposes significant requirements restricting changes in device design. If a device is cleared for marketing through the 510(k) process, the manufacturer may not change the device design in a manner that could affect safety or effectiveness significantly without an additional 510(k) clearance by the FDA. *See id.* § 807.81(a)(3)(i).

The medical device at issue in the present case is a Model 4011 cardiac pacemaker lead, which is part of a pacemaker system implanted in the body to assist the heart's natural beat. Pacemaker leads such as the Model 4011 transmit small electrical pulses to the heart from another part of the implanted system—a pacemaker pulse generator—and return

signals from the heart to the pulse generator. Pacemaker leads of the type at issue in this case are Class III devices for which no PMA is yet required. *See id.* § 870.3680(b), (c).

Petitioner Medtronic submitted a 510(k) application for the Model 4011 lead to the FDA, and the FDA required additional design information before it would make a decision on the application. On November 30, 1982, the FDA issued its substantial equivalence determination, which authorized marketing of the Model 4011 lead manufactured with the design reviewed and cleared by the FDA. *See* App. 6a.

B. This Litigation

On March 8, 1993, respondents filed this action in Florida state court, asserting claims of negligence, strict liability, and breach of implied warranty concerning an alleged pacemaker system failure. The matter was removed to the United States District Court for the Middle District of Florida pursuant to 28 U.S.C. §§ 1332(a) and 1441 as a diversity of citizenship case with an amount in controversy in excess of $50,000. The district court subsequently dismissed the implied warranty claim for failure to state a claim under Florida law. *See* App. 6a-7a.

On October 27, 1993, Medtronic moved for summary judgment on the ground that the FDCA preempted the remaining claims of negligence and strict liability. Although the district court initially denied the motion, App. 1d, it granted reconsideration because of the Eleventh Circuit's decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994), which had affirmed the preemption of negligence and strict liability claims under the FDCA. On March 16, 1994, the district court entered judgment for Medtronic on the ground that respondents' claims are preempted. App. 1b.

C. The Court of Appeals Opinion

The Eleventh Circuit affirmed the preemption of respondents' claims to the extent that they involved allegations of failure to warn or defective manufacture but reversed to the extent that the claims related to device design. The court of appeals based its analysis primarily upon the FDCA express preemption provision, 21 U.S.C. § 360k(a), and a comparison between state and federal requirements governing the Model 4011 lead.

Citing this Court's opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Eleventh Circuit held that "common law actions are state requirements within the meaning of § 360k(a)." App. 11a. Specifically, the court of appeals held that respondents' claims would create state requirements by asking a jury to determine how a reasonable manufacturer should design, manufacture, and provide warnings for the pacemaker lead at issue. App. 25a, 30a, 32a.

The court below then relied upon the following FDA regulation interpreting section 360k(a) to limit the types of federal requirements that would preempt different or additional state requirements:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d) (1995), *quoted in part at* App. 16a. The Eleventh Circuit deferred to the FDA's interpretive regulation, because it held that it was a "reasonable" construction

that "avoids a host of problems raised by a literal reading of § 360k(a)," whereas a literal reading of the statute "would infer broad preemptive intent." App. 16a. In so holding, the court of appeals rejected Medtronic's argument that under *Cipollone* the analysis should be "governed entirely by the express language" of the Act. App. 14a (quoting *Cipollone*, 505 U.S. at 517).

The Eleventh Circuit also rejected respondents' claim that the FDA's interpretive regulation limited preemption to circumstances in which a federal requirement is so specific that it only applies to a single type of device. Holding that the FDA regulation "does not suggest that the requirements themselves must mention the particular device in question," the court of appeals concluded that "[o]ur preemption inquiry must ask whether 'specific requirements' apply to a device, not whether the requirements specify the device." App. 19a. In support of its interpretation, the court below noted that other circuits have held that federal requirements applicable to numerous device types preempt common law claims. App. 20a-21a. Nonetheless, the court of appeals concluded that "preemption-triggering requirements should, in some way, be 'restricted by nature' to a particular process, procedure, or device and should not be completely open-ended." App. 21a-22a (footnote omitted).

Based upon its limiting definition of the term "requirement," the court of appeals held that there were federal requirements that preempted respondents' claims to the extent that they involved allegations of failure to warn or defective manufacture. According to the court's analysis, the failure to warn claims were preempted by the federal prescription device labeling regulation, 21 C.F.R. § 801.109, which specifies warnings that must be included in the labeling of prescription devices such as the Model 4011 lead. App. 32a. The court of appeals premised preemption of the

manufacturing claims upon the FDA's good manufacturing practice regulations, 21 C.F.R. pt. 820, which establish federal quality assurance standards for manufacturing. App. 30a.

However, the Eleventh Circuit also held that respondents' claims relating to device design were not preempted, because the court could not identify any federal design requirement that met its definition of that term as used in section 360k(a). In so holding, the court concluded that the FDA's review and clearance of the device's design through the 510(k) process did not preempt the design claims. App. 28a-29a. The court suggested that there could be no express preemption of design claims unless there were substantive federal requirements that "set the standard" for the device's design. *See* App. 25a. Because the FDCA does not specify such design standards, the court held that the respondents' design claims were not expressly preempted under section 360k(a). App. 29a.[2] The Eleventh Circuit's holding therefore preserved state law claims from express and implied preemption even though the claims exposed a manufacturer to state law liability for marketing a device design affirmatively authorized under a complex federal regulatory scheme.

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[2] The court of appeals also concluded that respondents' claims were not subject to implied preemption, because it could not identify any actual conflict between federal and state law. App. 10a n.5.

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS DECISION ESTABLISHES A DIRECT CONFLICT WITH DECISIONS OF OTHER COURTS OF APPEALS

The Eleventh Circuit's decision establishes a mature conflict among the circuits concerning the scope of federal preemption under the FDCA. Recent decisions of the Third and Fourth Circuits now conflict with decisions of the Fifth and Eleventh Circuits on the identical question—whether the FDCA preempts design claims involving a Class III device cleared for marketing under the 510(k) process. In addition, the principles underlying the Eleventh Circuit's opinion conflict directly with the premises of decisions by the First, Second, Seventh, and Eighth Circuits upholding preemption of design claims in closely analogous cases. The decisions of these four circuits in turn conflict fundamentally with a recent decision of the Ninth Circuit.

By denying preemption of design claims involving a Class III 510(k) device, the Eleventh Circuit's decision conflicts directly with recent decisions of the Third and Fourth Circuits. In *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), the Fourth Circuit considered whether the FDCA preempts negligence and strict liability claims for defective design of a Class III 510(k) device. In contrast to the court below, the *Duvall* court held that the 510(k) process was itself a federal requirement that preempted common law claims, including design claims. *Id.* at 399-400. *Duvall* emphasized that through the 510(k) process, the FDA reviews design information and then authorizes marketing a device with the particular design submitted. *Id.* at 399. In addition, because the 510(k) process substantially restricts changes in device design following initial clearance, the Fourth Circuit concluded that "for all intents and purposes, [the manufac-

turer] is required to continue to design . . . the device as proposed in its original 510(k) Notification." *Id.* at 399-400. The Fourth Circuit then held that these federal requirements expressly preempted common law claims alleging design defect. *Id.* at 401.

Similarly, in *English v. Mentor Corp.*, No. 94-1714, 1995 U.S. App. LEXIS 27670 (3d Cir. Sept. 29, 1995), the Third Circuit considered whether the FDCA expressly preempted state common law claims, including a negligent design claim, concerning a Class III 510(k) device.[3] The Third Circuit held that the 510(k) process was a federal "requirement" with preemptive effect within the meaning of section 360k(a). *Id.* at *15. The *English* court then concluded that the negligent design claim was expressly preempted, incorporating by reference the reasoning in two other Third Circuit cases that affirmed preemption of common law claims. *Id.* at *7, *19 (citing *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995)).

The Fifth Circuit has taken a position consistent with the conclusion of the Eleventh Circuit below, and therefore in direct conflict with the Third and Fourth Circuits, on the identical design claim issue. In *Feldt v. Mentor Corp.*, 61

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[3] Although the Third Circuit opinion did not specify which of these claims related to design, the district court opinion in *English* makes clear that the claims reviewed by the Third Circuit included "negligence in the design" of the device. *English v. Mentor Corp.*, No. 93-2725, 1994 U.S. Dist. LEXIS 7941, at *1 (E.D. Pa. June 10, 1994), *aff'd in part, rev'd in part*, No. 94-1714, 1995 U.S. App. LEXIS 27670 (3d Cir. Sept. 29, 1995).

F.3d 431 (5th Cir. 1995), the Fifth Circuit denied preemption of design claims involving a Class III 510(k) device. Like the Eleventh Circuit, the *Feldt* court premised its holding upon a conclusion that there were no federal design requirements giving rise to preemption under the FDCA. *Id.* at 437-38. At the present time, therefore, decisions of the Fifth and Eleventh Circuits conflict squarely with decisions of the Third and Fourth Circuits.

The conflict among the four circuits concerning the preemption of design claims also is mirrored in the lower federal and state courts, with some upholding preemption of design claims involving Class III 510(k) devices[4] and others denying preemption under the same circumstances.[5] In addition, the holding of one state supreme court cannot be reconciled with the holdings of the Third and Fourth Circuits. In *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992), the Supreme Court of Hawaii denied preemption of a common law claim involving a Class III 510(k) device on the ground that the 510(k) process does not impose preemptive federal requirements within the meaning of the FDCA. *Id.* at 1282. Even though the claim at issue was not explicitly described as a design claim, *Larsen* is consistent with the holdings of the Fifth and Eleventh Circuits, and inconsistent

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[4] *See, e.g., Caraballo v. Intermedics, Inc.*, 886 F. Supp. 974 (D.P.R. 1995); *Bokis v. American Medical Sys., Inc.*, 875 F. Supp. 748 (W.D. Okla. 1995); *Bollier v. Medtronic, Inc.*, No. H-92-2439, 1993 WL 734843 (S.D. Tex. Oct. 28, 1993).

[5] *See, e.g., Fender v. Medtronic, Inc.*, 887 F. Supp. 1326 (E.D. Cal. 1995) (dicta); *Sylvester v. Mentor Corp.*, No. 95-67, 1995 La. App. LEXIS 2490 (La. Ct. App. Sept. 20, 1995); *Fogal v. Steinfeld*, 620 N.Y.S.2d 875 (N.Y. Sup. Ct. 1994).

with the holdings of the Third and Fourth Circuits, regarding design claims.

Although the conflict among the Third, Fourth, Fifth, and Eleventh Circuits is direct, substantial, and irreconcilable, several other recent cases enhance the magnitude of the conflict over the scope of preemption under section 360k. The contradictions among the lower court holdings have spread to four other circuits that have not yet squarely decided whether design claims involving Class III 510(k) devices are preempted but have faced closely related issues. For example, the Eighth Circuit has denied preemption of design claims involving a Class II 510(k) device. *See National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 997 (8th Cir. 1994). Because the regulations governing the 510(k) process do not distinguish between Class II and Class III devices, the Eighth Circuit's opinion adds further confusion to the lower courts' jurisprudence concerning the design claim issue presented in this case.

Furthermore, the First, Seventh, and Eighth Circuits have affirmed preemption of design claims involving Class III devices approved for marketing through the PMA process.[6] Similarly, the Second and Seventh Circuits have affirmed preemption of design claims involving Class III devices cleared for clinical experimental use through the IDE proc-

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[6] *See King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Mitchell v. Collagen Corp.*, No. 94-3946, 1995 U.S. App. LEXIS 27709 (7th Cir. Oct. 2, 1995); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995).

ess.[7] The premises of these decisions conflict directly with the principles underlying the Eleventh Circuit's decision below and the Fifth Circuit's decision in *Feldt*. There is no relevant distinction between the federal design requirements imposed by the PMA process (held preemptive by the First, Seventh and Eighth Circuits), the IDE process (held preemptive by the Second and Seventh Circuits), and the 510(k) process implicated by the decisions of the Fifth and Eleventh Circuits.

Under the FDCA, the manufacturer, not the FDA, proposes the initial design of devices, regardless of whether they are cleared for distribution through the 510(k), PMA, or IDE processes.[8] Following careful individualized review, the FDA clears devices for distribution on a case by case basis with the particular design submitted, regardless of which of the three clearance processes is used.[9] Manufacturers are then prohibited from changing the FDA-authorized design of 510(k), PMA, and IDE devices in a way that could affect safety or effectiveness significantly without additional FDA clearance.[10] None of the three processes establishes preexisting substantive design standards. By concluding that federal design standards are prerequisite for preemption, the

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[7] *See Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995); *Slater v. Optical Radiation Corp.*, 961 F.3d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992).

[8] *See* 21 C.F.R. §§ 807.87 (510(k)); 814.20 (PMA); 812.20, 812.25, 813.20, 813.25 (IDE).

[9] *See id.* § 807.100 (510(k)); 21 U.S.C. § 360e(d)(1)(A) (PMA); 21 C.F.R. § 812.30 (IDE).

[10] *See* 21 C.F.R. §§ 807.81(a)(3)(i) (510(k)); 814.39(a) (PMA); 812.30(b)(1), 812.35(a)(1), 813.35(a)(9), 813.39(b)(1) (IDE).

Eleventh Circuit has taken a position inconsistent with the decisions of the First, Second, Seventh, and Eighth Circuits cited above, which have upheld preemption of design claims in the absence of such standards.[11]

The widespread and recurring conflicts described above call for prompt resolution by this Court. Because the scope of preemption varies among the circuits, national medical device manufacturers such as Medtronic, which do business in all fifty states, confront dramatic differences in liability exposure from state to state for the identical product design. In those circuits that have preserved liability for design claims by limiting preemption, variances among jury verdicts add further unpredictability for manufacturers that design new devices. This confusing and disjointed pattern of liability exposure interrupts the rational and efficient development, production, and sale of life-saving medical devices. Indeed, the current state of the law—in which manufacturers may either be insulated from, or exposed to, liability solely on the basis of the particular circuit in which a suit is filed—undermines the very purpose of the FDCA preemption provision. Congress enacted that provision to enhance uniformity of regulatory requirements so that the regulatory structure would not stifle technological innovations of vital importance to the public's health.

Until this Court resolves the conflict among the circuits, this burden on innovation will persist. This Court has never

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[11] These opinions of the First, Second, Seventh, and Eighth Circuits in turn conflict with the premises of a recent Ninth Circuit decision holding that the FDCA's express preemption provision does not encompass preemption of any common law claims. *See Kennedy v. Collagen Corp.*, No. 94-15197, 1995 WL 606511 (9th Cir. Oct. 17, 1995).

construed the express preemption provision of the FDCA, and it therefore has not yet provided a basis for the lower courts to resolve the conflict on their own. In addition, because the lower court opinions are premised upon the construction of a particular statutory provision that shows no sign of being amended in the near future, there is no reason to believe that additional cases in the foreseeable future will lead to a unification of the doctrine. Without Supreme Court guidance, the different circuits have felt free to disregard the opinions of other circuits. Each has forged its own construction of the statute, and there is no basis for concluding that they will reverse course. Thus, the conflict among the circuits is not likely to be resolved unless this Court grants review and establishes the uniformity that is so badly needed. Because the question of the scope of federal preemption under the FDCA has been litigated extensively in numerous lower courts, it is ripe for review in this Court.[12]

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[12] The various circuits have decided eleven other cases construing the FDCA preemption provision in addition to the eleven decisions discussed above. *See Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995); *LaMontagne v. E.I. du Pont de Nemours & Co.*, 41 F.3d 846 (2d Cir. 1994), *aff'g* 834 F. Supp. 576 (D. Conn. 1993); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989); *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Jacobs v. E.I. du Pont de Nemours & Co.*, No. 93-4144, 1995 U.S. App. LEXIS 29436 (6th Cir. Oct. 19, 1995); *Anguiano v. E.I. du Pont de Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994).

II. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT

A decision of this Court on the question presented would have widespread and profound effects upon the medical device industry and the consuming public, because it would define the scope of potential liability for the vast majority of the most critical medical devices. The Court certainly would resolve the scope of preemption concerning Class III 510(k) devices such as the Model 4011 lead, a question that is being litigated repetitively throughout the country with hopelessly inconsistent results. This matter is of critical importance because, as Congress noted in 1990, "over 80 percent of the devices that are potentially the most dangerous (Class III), enter the market" through the 510(k) process. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307. Class III 510(k) devices—which the FDCA defines as those purporting to be life-sustaining or life-supporting, or presenting a potentially unreasonable risk of illness or injury[13]—span the entire spectrum of critical medical technologies, from artificial hip joints to kidney dialysis systems to certain breast implants.[14] This Court should grant the petition for certiorari to resolve the scope of preemption concerning common law liability governing this vitally important category of medical products.

The present case is the proper vehicle for defining the scope of preemption for Class III 510(k) devices, because it clearly presents the one "hard issue" that has most divided

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[13] *See* 21 U.S.C. § 360c(a)(1)(C) (1994).

[14] *See* 21 C.F.R. §§ 888.3330, 876.5860, 878.3530 (1995).

the lower courts—whether common law claims involving the design of these devices are preserved or entirely foreclosed. As the numerous decisions cited above make clear, state law claims in medical device cases typically fall into one of three categories: labeling, manufacturing, or design. Although every circuit that has reviewed cases involving Class III 510(k) devices (including the court below) has affirmed preemption of claims relating to labeling or manufacturing,[15] the extension of preemption to design claims has proved more controversial.

The courts have divided over the design claim issue, because the federal requirements governing design under the 510(k) process differ from those governing labeling and manufacturing. Under the FDCA, the FDA has promulgated regulations establishing specific substantive standards for labeling and manufacturing independent of the requirements of the 510(k) process itself. The lower courts have relied on these regulations to a greater or lesser extent as the premise for upholding preemption of labeling and manufacturing

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[15] *See Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) (labeling and manufacturing claims preempted); *English v. Mentor Corp.*, No. 94-1714, 1995 U.S. App. LEXIS 27670 (3d Cir. Sept. 29, 1995) (labeling and manufacturing claims preempted, with the exception of express warranty claims); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995) (labeling and manufacturing claims preempted, with the exception of certain express warranty claims); *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995) (labeling claims preempted); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995) (App. 1a) (labeling and manufacturing claims preempted). Although *English* and *Duvall* established certain exceptions to preemption for express warranty claims, this Court recently has denied review of that issue. *See* Petition for Certiorari at i, *Shiley, Inc. v. Michael*, No. 94-1971, *cert. denied*, 116 S. Ct. 67 (Oct. 2, 1995).

claims.[16] In contrast, the primary federal requirements governing design of 510(k) devices are imposed through the 510(k) process itself rather than through particular pre-existing design standards. Through this complex regulatory process, the FDA reviews proposed designs, authorizes them for marketing, and prohibits significant changes in design without further authorization. This case therefore squarely presents the question whether the 510(k) process itself preempts common law claims (thereby foreclosing liability entirely) or leaves manufacturers exposed to viable lawsuits based upon device design.

The present case provides this Court with the best opportunity it has yet had to resolve the scope of FDCA preemption. This case is a "hard" case, because it involves both the agency review process and the particular category of common law claims that have most divided the lower courts. It is a very significant case, because a decision would affect over 80 percent of the most critical medical devices that enter the market. This Court should grant the petition in order to establish uniformity and certainty concerning the scope of liability for these medical products of vital importance to the public's health.

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[16] *See English*, 1995 U.S. App. LEXIS 27670, at *19; *Duvall*, 65 F.3d at 399; *Feldt*, 61 F.3d at 436; *Lohr*, App. 14a-18a.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

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November 13, 1995

APPENDICES

Lora Lohr, Michael Lohr, Her Husband, Plaintiffs-Appellants, v. Medtronic, Inc., a Foreign Corporation, Defendant-Appellee.	No. 94-2516

United States Court of Appeals,
Eleventh Circuit.

July 3, 1995.

Daniel C. Shaughnessy, Cowles & Shaughnessy, P.A., Robert F. Spohrer, Spohrer, Wilner & Maxwell, P.A., Jacksonville, FL, Brian Wolfman, Public Citizen Litigation Group, Washington, DC, for appellants.

Dennis P. Waggoner, Hill, Ward & Henderson, P.A., Tampa, FL, Marcus R. Magnuson, Medtronic, Inc., Minneapolis, MN, Daniel G. Jarcho, McKenna & Cuneo, Washington, DC, for appellee.

Appeal from the United States District Court for the Middle District of Florida.

Before Black and Barkett, Circuit Judges, and Roney, Senior Circuit Judge.

Black, Circuit Judge:

In this case we must decide whether the Medical Device Amendments of 1976 (MDA or Act), 21 U.S.C.A. §§ 360c-360l (West Supp.1994) preempt Appellants' state law negligent design, negligent manufacture, failure to warn, and strict liability claims against the manufacturer of an allegedly de-

fective pacemaker. The district court found that they did and dismissed the entire action. We hold that Appellants' negligent manufacture and failure to warn claims are preempted and affirm their dismissal. We also hold that Appellants' negligent design and strict liability claims are not preempted and therefore reverse their dismissal.

I. BACKGROUND

Because an understanding of the MDA's regulatory scheme is necessary to resolve the question of preemption, we begin with a brief outline of the Act.

A. The Regulatory Scheme

The market for medical devices was largely unregulated at the national level until the MDA's passage in 1976. With the MDA, Congress gave the federal Food and Drug Administration (FDA) comprehensive jurisdiction over all "devices intended for human use." 21 U.S.C.A. § 360c(a)(1). The text of the MDA reveals two competing congressional purposes relevant to this case:[1] (1) the MDA protects the public from unnecessary illness or injury by subjecting medical devices to a regulatory scheme designed to ensure that the devices are safe and effective, *see, e.g.*, 21 U.S.C.A. §§ 360c(a)(1)(A)(i); 360c(a)(1)(B); 360e(d)(2); and (2) the

[1] Nothing we say here should be interpreted as identifying the exclusive motives of Congress in passing the Act. Courts must be mindful of the fact that legislative acts reflect many competing interests and should not allow vague notions about a statute's overall purpose to overcome its plain text. *Mertens v. Hewitt Associates*, — U.S. ——, ——, 113 S.Ct. 2063, 2071, 124 L.Ed.2d 161 (1993).

MDA protects the public by encouraging the development and marketing of medical devices by crafting a nationally uniform regulatory scheme that prevents overregulation and thus ensures that development can be economically feasible, *see, e.g.*, 21 U.S.C.A. §§ 360j(g)(1); 360k(a).

These twin purposes are confirmed by the legislative history of the Act. For example, the House Report on the Act states:

> Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field.

H.R.Rep. No. 853, 94th Cong., 2d Sess. 10 (1976). Legislative history from the Senate reflects the same balancing of interests. *See* S.Rep. No. 33, 94th Cong., 1st Sess. 5, 12 (1975). The need to balance public safety with continued development was reiterated when Congress amended the MDA in 1990.

> Simply put, the [MDA] sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and the government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices.

S.Rep. No. 513, 101st Cong., 2d Sess. 13 (1990). The MDA thus reflects the intent of Congress to scrutinize the medical device industry to a greater extent without stifling innovation and development.

All medical devices regulated by the MDA fall into three statutory categories. Class I devices are those which pose little threat to the safety of the consuming public. These devices, including everything from tongue depressors to acoustic chambers, are subject only to the Act's generally applicable regulations. *See* 21 U.S.C.A. § 360c(a)(1)(A). Class II devices are those which pose enough of a safety hazard to require regulation beyond the general controls applicable to Class I devices. Class II devices, like tampons and oxygen masks, are consequently subject to device-specific special controls. *See* 21 U.S.C.A. § 360c(a)(1)(B).

Class III devices are those that the FDA determines are too unproven to be rendered safe by general controls or present a potential for unreasonable risk of illness or injury. Almost all life-sustaining medical devices, like pacemakers, are classified as Class III devices. In addition to the Act's general regulations and, in some instances, device-specific controls, Class III devices must generally undergo premarket approval (PMA) before the FDA will allow them into the marketplace. *See* 21 U.S.C.A. § 360c(a)(1)(C). The premarket approval process is a vigorous one, requiring the applicant to present the FDA with "all information" known or reasonably knowable about the device, including detailed information about the design, manufacture, uses, and labeling of the device. 21 U.S.C.A. § 360e(c)(1).

While the MDA contemplates that most Class III devices will reach the market through the PMA process, there are important exceptions. First, the MDA grandfathered into the market all devices introduced before May 28, 1976—the effective date of the Act. 21 U.S.C.A. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1994). Second, the MDA contains an investigational device exemption (IDE) for new devices under clinical investigation to determine their safety or effectiveness. 21 C.F.R. § 812.3(g). *See* 21 U.S.C.A. § 360j(g). In

order to foster the development of useful devices, IDE procedures allow manufacturers to begin limited marketing of new devices without undergoing the rigorous PMA process. 21 U.S.C.A. § 360j(g)(1).

Finally, a Class III device may reach the market without undergoing the PMA procedures if the device is found to be the "substantial equivalent" of an already-marketed device, including a device grandfathered into the market. 21 U.S.C.A. § 360e(b)(1)(B). For a device to qualify as the substantial equivalent of one which is already being marketed, the FDA must determine that the new device has the same intended use as the predicate device and either the same technological characteristics or the same safety and effectiveness as the predicate device. 21 U.S.C.A. § 360c(i)(1)(A). Every device entering the market as a substantial equivalent is subject to a premarket notification process (510(k) process) which allows the FDA to classify the device and make its substantial equivalence finding. 21 U.S.C.A. §§ 360(k); 360c(f)(1).

B. Facts[2]

This case arises from the failure of a pacemaker manufactured by Appellee Medtronic, Inc. The pacemaker in question, the Model 8403 Activitrax (Activitrax), is a Class III device under the MDA. 21 C.F.R. § 870.3610. The Activitrax has never been subject to the PMA process. *See* 21 C.F.R. § 870.3610(c).

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[2] For purposes of this appeal, we accept the facts in Appellants' complaint as true.

Appellant Lora Lohr was implanted with an Activitrax pacemaker in 1987. The pacemaker failed in 1990, forcing Ms. Lohr to endure emergency surgery to replace the Activitrax. According to Ms. Lohr's treating physician, the failure was caused by a defect in the pacemaker "lead"—the wire carrying electrical impulses from the pacemaker to the patient's heart tissues.

The Activitrax lead component, the Model 4011, is manufactured by Appellee as part of its pacemaker system. The FDA permitted marketing of the Model 4011 in 1982 after finding that it was the substantial equivalent of a device introduced prior to the effective date of the MDA. In other words, the Model 4011 entered the market through the 510(k) process as the substantial equivalent of a device grandfathered into the Act.

C. Procedural History

Appellants Lora and Michael Lohr originally brought this action in a Florida court, but Appellee removed the case to the Middle District of Florida based on diversity of citizenship. In their complaint, Appellants seek damages for injuries Lora Lohr allegedly sustained as a result of the Activitrax's failure and for Michael Lohr's alleged loss of consortium. The complaint contains four theories of liability: (1) negligent design; (2) negligent manufacture; (3) negligent failure to warn; and (4) strict liability in tort.[3]

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[3] The original complaint contained a breach of warranty claim which was dismissed for failure to state a claim under Florida law and is not at issue in this appeal.

Shortly after removing the case, Appellee moved for summary judgment, asserting that Appellants' claims were preempted by the MDA. The district court denied the motion in December 1993, but reconsidered its decision in light of this Court's decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994). Upon reconsideration, the district court granted Appellee's motion for summary judgment, interpreting Duncan as preempting all state law claims for negligence and strict liability. This appeal follows.[4]

II. DISCUSSION

The sole issue on appeal is whether the district court erred in holding that the MDA preempts all common law tort claims against a Class III device which entered the market

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[4] Prior to oral argument, Appellants sought to supplement their submissions to the Court with an additional brief. A similar request from Appellee and a request to reply to Appellee's supplemental brief inevitably followed. We carried these motions with the case. Appellants' supplemental brief appears to be a vehicle for bringing before the Court the FDA's amicus brief in *Talbott v. C.R. Bard, Inc.*, 1st Cir. No. 94-1951, a pending First Circuit case concerning preemption under the MDA. Litigating positions of an agency, as distinct from the agency's regulations, rulings, and practice, are entitled to no deference. *Martin v. OSHRC*, 499 U.S. 144, 154-56, 111 S.Ct. 1171, 1178, 113 L.Ed.2d 117 (1991); *Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 210-14, 109 S.Ct. 468, 473-74, 102 L.Ed.2d 493 (1988); *Alabama Dry Dock and Shipbuilding Corp. v. Sowell*, 933 F.2d 1561, 1563 (11th Cir.1991). Consequently, Appellants' supplemental brief would not aid the Court in resolving this case and we deny the motion to supplement. Appellee's motion to supplement and Appellants' supplemental reply are premised on consideration of Appellants' first supplemental brief, and our decision to reject that brief precludes the other submissions.

through the 510(k) process as the substantial equivalent of a grandfathered device.

A. Standard of Review

Statutory interpretation presents a question of law over which we exercise de novo review. *Barnett Bank of Marion County, N.A. v. Gallagher*, 43 F.3d 631, 633 (11th Cir.1995). We review an administrative agency's statutory interpretation de novo, but defer to an agency's interpretation if it is reasonable. *Asencio v. I.N.S.*, 37 F.3d 614, 616 (11th Cir.1994).

B. Preemption Under the MDA

The Constitution makes the laws of the United States "the supreme Law of the Land; ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding," U.S. Const. art. VI, cl. 2, and when federal and state laws conflict, the latter must give way, *CSX Transp., Inc. v. Easterwood*, — U.S. ——, ——, 113 S.Ct. 1732, 1737, 123 L.Ed.2d 387 (1993). Whether a federal statute preempts state law is a question of congressional intent. *Hawaiian Airlines, Inc. v. Norris*, — U.S. ——, ——, 114 S.Ct. 2239, 2243, 129 L.Ed.2d 203 (1994); *Forbus v. Sears Roebuck & Co.*, 30 F.3d 1402, 1405 (11th Cir.1994), *cert. denied*, — U.S. ——, 115 S.Ct. 906, 130 L.Ed.2d 788 (1995). Congressional enactment of a provision defining the preemptive scope of a statute implies that it intended to limit the preemptive scope of the statute to the express terms of the preemption provision. *Freightliner Corp. v. Myrick*, — U.S. ——, ——, 115 S.Ct. 1483, 1488, 131 L.Ed.2d 385 (1995); *Cipollone v. Liggett Group, Inc.*, — U.S. ——, ——, 112 S.Ct. 2608, 2618, 120 L.Ed.2d 407 (1992). In the absence of a "general, inherent conflict" between the state and federal law, review is limited to the express terms of the pre-

emption provision. *Freightliner*, — U.S. at ——, 115 S.Ct. at 1488 (quoting *Cipollone*, — U.S. at ——, 112 S.Ct. at 2618).

In determining the preemptive scope of the express language, however, several presumptions guide our analysis. First, preemption is appropriate only if it is the clear and manifest purpose of Congress. *Department of Revenue of Or. v. ACF Industries, Inc.*, — U.S. ——, ——, 114 S.Ct. 843, 851, 127 L.Ed.2d 165 (1994); *CSX*, — U.S. at ——, 113 S.Ct. at 1737; *United States v. Lot 5, Fox Grove, Alachua County, Fla.*, 23 F.3d 359, 361 (11th Cir.1994), *cert. denied*, — U.S. ——, 115 S.Ct. 722, 130 L.Ed.2d 627 (1995). Second, preemption of actions within the traditional police powers of a state "should not be lightly inferred." *Hawaiian Airlines*, — U.S. at ——, 114 S.Ct. at 2243 (quoting *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 21, 107 S.Ct. 2211, 2222, 96 L.Ed.2d 1 (1987)). Finally, there is a presumption against preemption if it would deny a party all judicial remedies. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251-52, 104 S.Ct. 615, 623, 78 L.Ed.2d 443 (1984); *Michael v. Shiley*, Inc., 46 F.3d 1316, 1326 (3rd Cir.1995). Although the presumptions against preemption cannot drive our analysis and must yield to a clear expression of congressional intent, in a close case the presumptions tip our statutory interpretation against preemption. *See Cipollone*, — U.S. at ——, 112 S.Ct. at 2618; *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-85, 112 S.Ct. 2031, 2037, 119 L.Ed.2d 157 (1992).

Preemption under the MDA is governed by the Act's preemption provision,[5] which states:

> Except as provided in subsection (b) of this section [delineating an exemption procedure not relevant to this case], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a). To determine whether Appellants' claims are preempted by the MDA, we must compare the "State . . . requirement[s]" under which the suit was brought with MDA-imposed requirements. Before comparing Appellants' claims with the requirements imposed on the Activitrax by the MDA, however, we must address two threshold questions: (1) what constitutes a "State . . . requirement" and (2) what constitutes a "requirement" under the MDA. 21 U.S.C.A. § 360k(a).

[5] Both parties accept the preemption provision as controlling. Although the Supreme Court recently explained that implied preemption is sometimes appropriate despite the existence of an express preemption provision, *see Freightliner*, — U.S. at ——, 115 S.Ct. at 1487-88, we doubt that this is such a case. First, it does not seem impossible for a manufacturer to comply with the MDA's requirements and any additional requirements which Appellants' suit might add. *See id.* — U.S. at ——, 115 S.Ct. at 1488. Second, it does not appear that Appellants' suit would frustrate "the full purposes and objectives of Congress." *Id.*

1. State Requirement.

To determine what § 360k(a) means by a "State . . . requirement different from, or in addition to" MDA requirements, we must consider whether Congress intended to include state common law actions.[6] Were we writing on a clean slate, this might present a difficult question, but we do not write on a clean slate. In *Duncan v. Iolab Corp.*, 12 F.3d 194, this Court adopted the Seventh Circuit's reasoning in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, — U.S. ——, 113 S.Ct. 327, 121 L.Ed.2d 246 (1992), and held that the MDA preempted a plaintiff's negligence, strict liability, and breach of implied warranty claims. Thus, the law of this Circuit is that the phrase "State . . . requirement" in § 360k(a) includes state common law tort actions. *See also Cipollone*, — U.S. at ——, 112 S.Ct. at 2620 ("The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law") (quoting 15 U.S.C. § 1334(b)). Every circuit to consider the question agrees that common law actions are state requirements within the meaning of § 360k(a).[7]

[6] Appellants' initial brief did not appear to dispute whether their claims were based on state requirements within the meaning of § 360k(a). Their reply brief, however, appears to dispute the issue in this appeal.

[7] *See Mendes v. Medtronic, Inc.*,, 18 F.3d 13, 16 (1st Cir.1994); *Michael*, 46 F.3d at 1323 (3rd Cir.); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 304 (5th Cir.1995); *Slater*, 961 F.2d at 1332-33 (7th Cir.); *Martello*

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The existence of a savings clause within the MDA cannot alter this conclusion. The savings clause states that "[c]ompliance with an order [under the MDA] shall not relieve any person from liability under Federal or State law." 21 U.S.C.A. § 360h(d). While the savings clause almost certainly prohibits a holding that the MDA preempts all state law liability, our interpretation of § 360k(a) does not preclude all liability. Further, nothing in the savings clause suggests that some tort liability, as opposed to other types of liability, must be preserved. Interpreting the savings clause to preserve non-tort liability, such as contract liability, is not only permissible, but also comports with the Supreme Court's interpretation of a savings clause in a recent preemption case. *See American Airlines, Inc. v. Wolens*, — U.S. ——, ——, 115 S.Ct. 817, 826, 130 L.Ed.2d 715 (1995) (holding that the Airline Deregulation Act preempts claims under the Illinois Consumer Fraud and Deceptive Business Practices Act but does not preempt state breach of contract actions). Moreover, where the preemptive intent of Congress is clear, a general savings clause cannot supersede the specific preemption provision. *Morales*, 504 U.S. at 383-85, 112 S.Ct. at 2037. In short, as long as we interpret § 360k(a) as permitting some state law liability, the MDA's savings clause simply begs the question of what liability it preserves.

Appellants' reply brief suggests that their negligent manufacturing and failure to warn claims are exempt from preemption under § 360k(a) because the claims may dem-

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v. CIBA Vision Corp., 42 F.3d 1167, 1168 (8th Cir.1994); *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 809 (9th Cir.1995).

onstrate a violation of the MDA's own requirements and, therefore, do not constitute state requirements "different from, or in addition to" the Act's requirements. While we ordinarily do not address arguments first raised in a reply brief, *Allstate Ins. Co. v. Swann*, 27 F.3d 1539, 1542 (11th Cir.1994), we will exercise discretion to reach this question because the law in this Circuit forecloses Appellants' argument.[8]

Papas v. Upjohn Co., 985 F.2d 516 (11th Cir.), *cert. denied*, — U.S. ——, 114 S.Ct. 300, 126 L.Ed.2d 248 (1993), considered the scope of preemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 7 U.S.C.A. §§ 136-136y. In *Papas*, the plaintiffs, like Appellants in this case, argued against preemption by claiming that their common law action would show a violation of the EPA's own FIFRA labeling standards. Therefore, the plaintiffs claimed that their suit was not a "requirement . . . in addition to or different from" FIFRA's labeling requirements. *Papas*, 985 F.2d at 518-19 (quoting 7 U.S.C.A. § 136v). We rejected the argument, noting that "it is for [the agency], not a jury, to determine whether labelling and packaging information is incomplete or inaccurate, and if so what label changes, if any, should be made." *Id.* at 519. We believe *Papas* controls here and hold that preemption under the MDA cannot be defeated by a common-law suit alleging a

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[8] We assume, arguendo, that Florida common law would recognize an action whose standard of care is defined by the standards of the MDA and that Appellants' complaint may be read broadly enough to encompass such an action.

violation of the statutory standards. Every circuit court decision addressing this issue under the MDA agrees.[9]

2. Requirements Under the MDA.

a. The FDA's Preemption Regulations.

Where the plain meaning of the express terms of a statute is unclear, we may defer to a reasonable interpretation adopted by the agency charged with enforcing the statute. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-44, 104 S.Ct. 2778, 2782, 81 L.Ed.2d 694 (1984). Appellants insist that the meaning of "requirements" as used in § 360k(a) is unclear and that we should therefore defer to the FDA regulations clarifying the meaning of "requirements."[10]

Appellee responds that under the express preemption rule enunciated in *Cipollone v. Liggett Group, Inc.*, our analysis should be "governed entirely by the express language" of the Act. *Cipollone*, — U.S. at ——, 112 S.Ct. at 2618. Alternatively, Appellee argues that the FDA's regulations are contrary to the clear intent of Congress and, therefore, are not entitled to deference. We disagree.

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[9] *Michael*, 46 F.3d at 1328-29; *Reeves*, 44 F.3d at 307; *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 992 n. 2 (8th Cir.1994); *King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir.) (opinion of Aldrich and Campbell, JJ.), *cert. denied*, — U.S. ——, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993).

[10] Congress empowered the FDA to promulgate regulations to enforce the MDA. *See* 21 U.S.C.A. § 371(a).

Cipollone did not prohibit reliance on an agency's preemption regulations. While the opinion speaks only of "the express language" of the statutes, neither of the statutes examined in *Cipollone* had regulations interpreting its preemptive scope and nothing in the opinion indicates that the issue of preemption regulations was ever raised or considered. Appellee's argument thus asks us to find a sub silentio holding in *Cipollone*, something which courts are reluctant to do. *See Federal Election Com'n v. NRA Political Victory Fund*, — U.S. ——, ——, 115 S.Ct. 537, 542, 130 L.Ed.2d 439 (1994). Moreover, the Supreme Court has deferred to FDA preemption regulations in the past, *see Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-14, 105 S.Ct. 2371, 2375-76, 85 L.Ed.2d 714 (1985), and has examined another agency's preemption practices in at least one post-*Cipollone* case, *see Wolens*, — U.S. at ——, 115 S.Ct. at 825 (discussing the Department of Transportation's interpretation of its authority to displace courts in air carrier contract disputes). We are therefore unable to conclude that *Cipollone* created an express preemption rule which forecloses our examination of the FDA's regulations.

The principles guiding deference to an agency's interpretation of a statute are well established. First we must ask whether Congress has spoken directly to the precise question. *NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, — U.S. ——, ——, 115 S.Ct. 810, 813, 130 L.Ed.2d 740 (1995); *Chevron*, 467 U.S. at 841-43, 104 S.Ct. at 2781. If the statute does directly address the precise question, an agency interpretation to the contrary is entitled to no deference; if not, the Court must inquire into whether the agency's interpretation is reasonable. *NationsBank*, — U.S. at ——, 115 S.Ct. at 813-14; *Chevron*, 467 U.S. at 843-44, 104 S.Ct. at 2782. We defer to the agency's interpretation unless it is

"arbitrary, capricious, or manifestly contrary to the statute." *Chevron*, 467 U.S. at 844, 104 S.Ct. at 2782.

Congress's choice of the word "requirement" in § 360k(a)(1), does not speak directly to the precise issue of whether Appellants' state common law tort claims are preempted by the MDA. As used in § 360k(a), a "requirement" refers to a legal obligation, *see Brown v. Gardner*, — U.S. ——, ——, 115 S.Ct. 552, 555, 130 L.Ed.2d 462 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context") and the corresponding definition is "something called for or demanded," Webster's New International Dictionary 1929 (3d ed. 1976). *See Asgrow Seed Co. v. Winterboer*, — U.S. ——, ——, 115 S.Ct. 788, 793, 130 L.Ed.2d 682 (1995) (stating that undefined statutory terms should be given their ordinary meaning). Even using this ordinary meaning, the scope of the word "requirement" is ambiguous and consideration of the FDA's interpretation is appropriate.

In defining the scope of § 360k(a), the FDA has indicated that:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . .

21 C.F.R. § 808.1(d) (emphasis added). We believe that this narrowing of the meaning of "requirement[s]" applicable . . . to the device" to "specific counterpart regulations" or "specific requirements applicable to a particular device" is reasonable because it avoids a host of problems raised by a literal reading of § 360k(a). First, an expansive reading of § 360k(a) would infer broad preemptive intent in the face of well-settled presumptions against such a construction. *See, e.g., ACF Industries*, — U.S. at ——, 114 S.Ct. at 851. Second, the broadest construction of § 360k(a) would call into question almost all state law liability pertaining to MDA-regulated manufacturers. Such an interpretation would render the MDA's savings clause, 21 U.S.C.A. § 360h(d), meaningless, violating a cardinal rule of statutory construction which avoids interpretations which render a statutory provision superfluous, *see Ratzlaf v. United States*, — U.S. ——, ——, 114 S.Ct. 655, 659, 126 L.Ed.2d 615 (1994). Third, although a state PMA requirement would logically be preempted by a literal reading of § 360k(a), the Act's legislative history suggests that such practices should not be preempted. H.R.Rep. No. 853, 94th Cong., 2d Sess. 45-46 (1976).[11]

Because Congress left open the question of what MDA "requirements" preempt competing state requirements, the FDA's addition of the word "specific" is a reasonable interpretation of the statute. By clarifying the statutory term "requirement" to mean "specific requirements," the FDA's preemption regulation stayed within the zone of reasonableness required of agency interpretations. *See Chevron*, 467 U.S. at 843-44, 104 S.Ct. at 2782-83. Finally, we note that every court decision which the parties have brought to our

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[11] The House Report cited California's premarket clearance program with approval as an example of practices which the FDA should exempt from preemption under § 360k(b). H.R.Rep. No. 853, 94th Cong., 2d Sess. 45-46 (1976). Nevertheless, we believe the statement is relevant to our interpretation of § 360k(a) by demonstrating that Congress had no desire to completely occupy the field of medical device regulation.

attention either explicitly[12] or implicitly[13] regards the preemption regulations as valid. We hold that the FDA's preemption regulations are a reasonable interpretation of § 360k(a) entitled to deference by the Court.

b. MDA Specific Requirements.

Although the FDA's clarification of § 360k(a) is helpful, we must still struggle with defining what "specific requirements" under the MDA trigger preemption. *See* 21 C.F.R. § 808.1(d). Appellants interpret the regulations to mean that in this case preemption is proper "only if there are federal requirements imposed specifically upon manufacturers of pacemakers regarding" design, manufacture, or warnings. In other words, Appellants take the position that only MDA regulations which state that "a pacemaker manufacturer must do . . ." can constitute "specific requirements" triggering preemption. Appellees, on the other hand, argue that the regulations cannot be interpreted to require device specificity.

A careful reading of the FDA's MDA preemption regulations does not support the device-specific interpretation Appellants seek to impose. Significantly, the regulations allow preemption "when [1] the Food and Drug Administration has established specific counterpart regula-

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[12] *See, e.g., Martello*, 42 F.3d at 1168; *King*, 983 F.2d at 1134; *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273, 1281 (Hawaii 1992); *Ginochio v. Surgikos, Inc.*, 864 F.Supp. 948, 952 (N.D.Cal.1994).

[13] *See, e.g., Michael*, 46 F.3d at 1324; *Anguiano*, 44 F.3d at 809; *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543-44 (3rd Cir.), *cert. denied*, — U.S. ——, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994); *Mendes*, 18 F.3d at 16; *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1424 n.8 (5th Cir.), *cert. denied*, — U.S. ——, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993).

tions or [2] there are other specific requirements applicable to a particular device under the act[.]" *Id.* (emphasis supplied). The word "or" in the regulation indicates that the FDA intended the two conditions for preemption to be alternatives so that the existence of either condition triggers preemption. *See Hawaiian Airlines*, — U.S. at ——, 114 S.Ct. at 2245. While the first condition, the existence of "specific counterpart regulations," might be read to require device specificity, the second condition cannot.

The most natural reading of the FDA's "specific requirements" language requires specificity in the nature of the requirements, not in their applicability to designated devices. The "applicable to a particular device" language, mirroring the statute, requires a court to ask whether the requirements in question apply to the device in question. *See* 21 U.S.C.A. § 360k(a); 21 C.F.R. § 808.1(d). That language does not suggest that the requirements themselves must mention the particular device in question. Our preemption inquiry must ask whether "specific requirements" apply to a device, not whether the requirements specify the device.

Construing the FDA's preemption regulations to require device specificity also contradicts the structure of the Act. Under the MDA, Class III devices are subject to the highest level of scrutiny through the PMA process.[14] *See* 21

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[14] The comparative costs of market entry under the MDA supports the conclusion that the PMA process presents the highest obstacle. While the average price-range of market entry through the premarket notification 510(k) procedure is $50 to $2,000, the equivalent range for devices undergoing the PMA process is $111,000 to $828,000. Robert B. Leflar, Public Accountability and Medical Device Regulation, 2 Harv.J.L. & Tech. 1, 47 (1989).

U.S.C.A. § 360c(a)(1)(C). *Accord Martello*, 42 F.3d at 1168; *Stamps*, 984 F.2d at 1419. Yet the PMA procedure's "requirements" under the MDA are not device-specific. Instead, the PMA process requires manufacturers to submit to an approval process standardized for all Class III devices. *See, e.g.*, 21 U.S.C.A. § 360e(c)-(d); 21 C.F.R. §§ 814.1-814.45. It would be anomalous for the MDA to preempt certain claims which conflict with device-specific requirements placed on Class II devices, *see National Bank*, 38 F.3d at 990; *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 247 (5th Cir.1989), but not preempt claims against devices subject to the MDA's most rigorous, albeit non-device-specific, procedures.[15] Thus, the overall structure of the MDA supports interpreting the FDA's preemption regulations as not requiring device specificity.

Finally, a device-specific requirement is contrary to the clear weight of authority. Although some reported decisions demand that an MDA's "requirement" be device-specific, *see Larsen*, 837 P.2d at 1282; *Ginochio*, 864 F.Supp. at 953; *Oja v. Howmedica, Inc.*, 848 F.Supp. 905, 906-07 (D.Colo.1994), only the Ninth Circuit appears to accept this position,[16]

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[15] Claiming that the PMA procedures are device-specific requirements because they subject each device to particularized attention proves too much. For example, if the device-specific examination of a PMA application under non-specific regulations allows us to characterize the PMA procedures as device-specific, then the individualized examination of a 510(k) application, *see* 21 U.S.C.A. § 360(k); 21 C.F.R. §§ 807.87-807.100, allows us to characterize the 510(k) procedure as device-specific.

[16] While *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846 (2nd Cir.1994) upholds a district court decision requiring device-

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Anguiano, 44 F.3d at 809. Significantly, the First, Third, Fifth, and Eighth Circuits' MDA preemption decisions reject reading any device-specific requirement into § 360k(a) and its regulatory clarification. *See Michael*, 46 F.3d at 1324 (3rd Cir.); *Reeves*, 44 F.3d at 304-05 (5th Cir.); *Martello*, 42 F.3d at 1169 (8th Cir.); *Mendes*, 18 F.3d at 17-19 (1st Cir.).

Nevertheless, our rejection of Appellants' interpretation of the FDA regulations does not remove all significance from the FDA's choice of the word "specific." While a precise definition of what the FDA means by "specific requirements" is neither possible nor desirable, the term must at least narrow the potentially unlimited scope of preemption under § 360k(a). Starting with the plain meaning of the term "specific," defined inter alia as "having a real and fixed relationship to [and] restricted by nature to a particular individual, situation, relation, or effect," Webster's New International Dictionary 2187 (3d ed. 1976), the FDA's call for "specific requirements" under the MDA and the interpretive presumptions against preemption, *see Hawaiian Airlines*, — U.S. at ——, 114 S.Ct. at 2243; *ACF Industries*, — U.S. at ——, 114 S.Ct. at 851; *Silkwood*, 464 U.S. at 251-52, 104 S.Ct. at 623, preclude an overly-broad reading of the Act's preemptive scope.[17] We hold that preemption-trigger-

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specificity, *see Lamontagne v. E.I. Du Pont de Nemours & Co.*, 834 F.Supp. 576, 582-83 (D.Conn.1993), it does so by affirming the district court's dismissal of the complaint on non-preemption grounds and does not address the issue of preemption under the MDA.

[17] For example, equating the FDA's broad power to monitor the medical device market and intervene in the market when necessary, *see, e.g.* 21 U.S.C.A. §§ 331-334, with the type of "specific requirements"

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ing requirements should, in some way, be "restricted by nature" to a particular process, procedure, or device[18] and should not be completely open-ended.

C. Preemption of Appellants' Claims

Having laid out the general rules of preemption under the MDA, we must now conduct a claim-by-claim inquiry to determine whether Appellants' state law claims are preempted.

The MDA preempts a state or local "requirement" which is both "different from, or in addition to" a specific MDA requirement, and "relates to the safety or effectiveness" or "any other matter" included in a specific MDA requirement. 21 U.S.C.A. § 360k(a). *See also* 21 C.F.R. § 808.1(d). We have already determined that state common law claims can impose state requirements within the meaning of the MDA and that these state requirements must be compared with those spe-

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necessitating preemption would stretch the regulation's language, and the preemptive scope of the MDA, beyond the bounds of reason. The possession of jurisdiction is not synonymous with making requirements. A rule equating jurisdiction with preemption-triggering requirements would infer absolute preemption whenever Congress legislates. Such a rule "is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence." *Hillsborough County*, 471 U.S. at 717, 105 S.Ct. at 2377; *Moore*, 867 F.2d at 245.

[18] Device-specific requirements will often be "specific requirements" triggering preemption. *See* 21 C.F.R. § 808.1(d). This does not mean that specific requirements must be device-specific.

cific MDA requirements applicable to the device at the heart of the suit. We must now determine whether Appellants' claims are "different from or in addition to" and "relate to any matter" included in a specific MDA requirement. 21 U.S.C.A. § 360k(a).

The narrow focus of our inquiry should be emphasized. In this section we examine only preemption of state common law claims against the manufacturer of a Class III device which entered the market via the 510(k) process as the substantial equivalent of a grandfathered device. This narrow focus often limits the usefulness of the authorities both parties rely upon. For example, Appellee's heavy reliance on *Stamps*, 984 F.2d 1416, and *King*, 983 F.2d 1130, is misplaced because the device at issue in those cases had undergone the full PMA process before it entered the market.

Our narrow focus also precludes Appellants' reliance on *Smith v. Pingree*, 651 F.2d 1021 (5th Cir., Unit B 1981). First, *Smith* was decided prior to the Supreme Court's *Cipollone* decision and relied on implied preemption principles to reach its decision. *Smith*, 651 F.2d at 1024 (citing *Chemical Specialties Mfrs. Assn., Inc. v. Clark*, 482 F.2d 325, 327 (5th Cir.1973)). *See also id.* at 1025. *Cipollone* made clear that in the absence of some "cause to look beyond" an express preemption provision, implied preemption principles should not be used to decide the preemptive scope of a statute in which Congress provided an express preemption provision.[19] *Cipollone*, — U.S. at ——, 112 S.Ct. at

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[19] We also note that the Fifth Circuit has ignored *Smith* in its post-*Cipollone* MDA preemption cases. *See Reeves*, 44 F.3d 300; *Stamps*, 984 F.2d 1416.

2618. *See also Freightliner*, — U.S. at ——, 115 S.Ct. at 1488. Second, *Smith* is factually distinguishable from the instant case because it considered the preemptive scope of the MDA's Class II regulations on a state regulatory statute. *Smith*, 651 F.2d at 1022 (citing Fla.Stat. §§ 468.135(7); 468.136(1)-(2)). Third and most importantly, the result in *Smith* relies on the fact "that the Florida statute does not relate 'to a matter included in a federal requirement applicable to a device.' " *Smith*, 651 F.2d at 1025 (quoting 21 U.S.C.A. § 360k(a)(2)). *See also id.* at 1024 (holding that § 468.135(7) is not preempted because it addresses a different concern than does the MDA). In other words, *Smith* found that the state statute at issue did not relate to the safety and effectiveness or to "any other matter" within the MDA. *See* 21 U.S.C.A. § 360k(a)(2). In contrast, Appellants cannot seriously dispute that their tort action relates to the safety of the Activitrax. Thus, *Smith* provides no guidance in deciding the case before us.

1. Negligent Design.

Appellants' complaint alleged that Appellee breached its duty of care to Lora Lohr by negligently designing and testing the Activitrax pacemaker. Appellants contend that the district court erred by dismissing this claim because the Activitrax and its Model 4011 lead were never subject to any specific requirements under the MDA within the meaning of the Act's preemption provision. Appellee responds that the district court correctly found Appellants' claim preempted because the Activitrax is subject to numerous requirements under the MDA. We conclude that none of the regulations applicable to the Activitrax constitute specific requirements under the MDA and therefore reverse the district court's preemption of Appellants' negligent design claim.

Appellants' Florida law negligent design claim could certainly impose a "State . . . requirement" upon the Activitrax. 21 U.S.C.A. § 360k(a). As explained above, congressional use of the term "requirement" sweeps broadly to encompass common law, as well as statutory and regulatory requirements. *Cipollone*, — U.S. at ——, 112 S.Ct. at 2620, *Duncan*, 12 F.3d at 195. Appellants' negligent design action would ask the jury to decide if Appellee did "something that a reasonably careful person would not do under like circumstances or . . . fail[ed] to do something that a reasonably careful person would do under like circumstances." Florida Standard Jury Instructions in Civil Cases § 4.1. If the MDA establishes specific requirements that apply to the design of the Activitrax, Appellants' action would ask the jury to declare what constitutes a reasonable design after the MDA already set the standard. By doing so, Appellants' claim would be "different from or in addition to" the MDA standard, would "relate . . . to [a] matter included" in the MDA, and would, therefore, be preempted. *See* 21 U.S.C.A. § 360k(a). *See, e.g.*, *National Bank*, 38 F.3d at 991; *Gile*, 22 F.3d at 544; *Slater*, 961 F.2d at 1333. In sum, if the FDA, pursuant to its authority under the MDA, has imposed specific requirements on the Activitrax, a jury cannot add any requirements. *See, e.g.*, *Papas*, 985 F.2d at 518. Appellee identifies four ways in which the MDA allegedly imposes specific requirements on the Activitrax and its Model 4011 lead. We consider each in turn.

First, Appellee insists that the FDA's approval of the Model 4011's 510(k) submission constitutes a finding that the device is safe and effective under the Act—a finding Appellee equates to a specific requirement. Even assuming that a safety and effectiveness finding would constitute a specific design requirement under the MDA, we are not

convinced that 510(k) approval constitutes a finding of safety and effectiveness.

A finding of "substantial equivalence" by the FDA means that the new device has the same intended use as the original device and that the new device either has the same technological characteristics as the original or is demonstrated to be as safe and effective as the original device. 21 U.S.C.A. § 360c(i)(1)(A).[20] Thus, while a substantial equivalence finding can be a finding of safety and effectiveness, there is no way to tell whether a given substantial equivalence finding is a finding of safety and effectiveness. Moreover, the FDA's regulations explain that approval of a device under 510(k) procedures as the substantial equivalent to a grandfathered device "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. This regulation makes obvious sense because the FDA could hardly find a device "as safe and effective" as a grandfathered device whose safety and effectiveness were never established by MDA procedures. *See* 21 U.S.C.A. § 360c(i)(1)(A)(ii)(I). The lack of any official approval under the 510(k) procedure was made clear to Appellee when the Model 4011 was approved in 1982. The FDA's clearance letter, tracking the language of the regulations, cautioned Appellee that "[t]his letter does not in any way denote official FDA approval of your device."

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[20] This section did not exist when the Model 4011 was approved, but we accept for these purposes that the new section only codified the prior practice of the FDA. *See* S.Rep. No. 513, 101st Cong., 2d Sess. 28 (1990).

The regulations governing the form and content of a 510(k) submission state that the "summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence." 21 C.F.R. § 807.92(a). Thus, the MDA's 510(k) submission regulations clarify what should be obvious from the statute: The 510(k) process is focused on equivalence, not safety, and the question of whether a device has been deemed safe and effective cannot be resolved by looking at the 510(k) process, but must be determined by looking at the process through which the original device entered the market. We therefore reject Appellee's argument that 510(k) approval constitutes a finding of safety and effectiveness within the Act.[21] *Cf. National Bank*, 38 F.3d at 998 (Loken, J., concurring) (noting that "an FDA order permitting the new device to be marketed as substantially equivalent to existing devices would not normally reflect agency approval"). We hold that 510(k) approval under the MDA, standing alone, is not a finding of safety and effectiveness and does not impose specific requirements on a device for preemption purposes.

Second, Appellee suggests that by grandfathering pre-MDA devices into the market, the Act recognized their safety and effectiveness as historically established. We disagree. "[T]he absence of a federal standard cannot implicitly extinguish state common law." *Freightliner*, — U.S. at ——, 115 S.Ct. at 1485. Moreover, Appellee identifies nothing in

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[21] Surprisingly, Appellee does not cite to 21 C.F.R. § 807.94, which requires Class III 510(k) submissions to be identified as such. While that regulation provides a scintilla of support to Appellee's argument that a 510(k) submission is a safety and effectiveness finding, it is not enough to overcome our conclusion.

the statute's text, or even in its legislative history, to suggest that grandfathering constitutes a safety and effectiveness finding. Given the strong presumptions against the preemption of state common law claims, we find this argument without merit.

Recognition of the MDA's competing purposes supports our conclusion that grandfathering, without more, cannot justify preemption under the Act. The MDA represents congressional balancing of at least two competing purposes: the desire to protect the public from unsafe devices and the desire to encourage innovation and development in the biomedical technology field. *See, e.g.* H.R.Rep. No. 853, 94th Cong., 2d Sess. 10-11 (1976); S.Rep. No. 33, 94th Cong. 1st Sess. 10 (1975). In light of this balancing, we can view the MDA as a compromise between device manufacturers and Congress. In exchange for the financial and time burdens placed upon manufacturers by the MDA, the manufacturers were assured a nationally uniform and predictable regulatory and liability climate. A rule preempting liability based on grandfathering would give the benefits of a uniform, predictable liability climate to devices that never paid the MDA's regulatory "price" for market entry. Additionally, allowing state tort suits based upon the failure of pre-MDA devices would not disturb a manufacturer's developmental calculus because presumably, when such devices were first introduced, the devices were considered a wise business investment despite state-imposed tort liability. In short, preempting claims against grandfathered pre-MDA devices would give their manufacturers a regulatory windfall.

Third, Appellee points to continued FDA surveillance of devices like the Activitrax as constituting specific requirements under the Act. *See, e.g.*, 21 C.F.R. §§ 807.81(a)(3)(i) (requiring FDA approval for any design changes); 895.25 (granting FDA authority to order labeling changes). As already explained above, these provisions cannot constitute specific requirements within the meaning of the MDA's preemption regulation. At best, they are general requirements because they have no "fixed relationship" and are not "restricted by nature to" a particular process, procedure, or device. *See* Webster's New International Dictionary 2187 (3d ed. 1976). In light of the presumption against preemption, the FDA's jurisdiction to monitor the market is too slender a regulatory strand to support preemption.

Finally, Appellee suggests that MDA procedures for classifying devices impose specific requirements. *See* 21 U.S.C.A. § 360c(a); 21 C.F.R. § 860.7. As we have previously noted, a "requirement" is best understood as "something called for or demanded." Webster's New International Dictionary 1929 (3d ed. 1976). Putting a device into Class III, without more, places no demands on the device's manufacturer. *Accord National Bank*, 38 F.3d at 997. The classification of devices under the Act is similar to a regulatory census; while the classification may have significant regulatory consequences, it creates no requirements by itself.

Accordingly, we hold that Appellants' negligent design claim is not preempted by the MDA because the Act does not establish any specific design requirements, through a finding of safety and effectiveness or otherwise, which conflict with the state law claim.

2. Negligent Manufacture.

Appellants' complaint alleged that Appellee breached its duty of care to Lora Lohr by negligently manufacturing and assembling the Activitrax and Model 4011. The district court found that the MDA preempted this negligent manufacturing claim. After reviewing the requirements the MDA places on

the manufacturing processes of suppliers like Appellee, we affirm the district court.

Like their negligent design claim, Appellants' negligent manufacturing claim could create state requirements because it would ask a jury to determine how a reasonable manufacturer should build the Activitrax. Therefore, the negligent manufacturing claim is preempted if the jury could create a standard of conduct "different from, or in addition to" a specific MDA requirement. *See* 21 U.S.C.A. § 360k(a).

As we have already concluded, nothing in the MDA's 510(k) approval procedures, grandfathering provision, oversight and enforcement powers, or classification requirements constitutes a "specific requirement" justifying preemption under the Act. *See* 21 C.F.R. § 808.1(d). In the case of manufacturing, however, Appellee also points to the MDA's good manufacturing practice (GMP) regulations as specific requirements justifying preemption. *See* 21 U.S.C.A. § 360j(f); 21 C.F.R. §§ 820.1-820.198.

The GMP regulations monitor the "methods used in, and facilities and controls used for, the manufacture, pre-production design validation (. . . but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device . . . to assure that the device will be safe and effective. . . ." 21 U.S.C.A. § 360j(f)(1)(A). As the statute's text makes clear, although GMP requirements do not evaluate the safety and effectiveness of the device, the GMP requirements do ensure that the manufacturing, packing, and other processes associated with a manufacturing enterprise are conducted safely and effectively. *Id.* The GMP regulations include requirements affecting a manufacturer's organization, personnel, building, equipment, component controls, production and process controls, packaging, labeling controls, holding, distribution, installation, device evaluation, and record keeping. *See* 21 C.F.R. §§ 820.20-820.198.

We believe the GMP requirements are specific requirements which preempt Appellants' negligent manufacturing claim. *Accord Michael*, 46 F.3d at 1324; *Mendes*, 18 F.3d at 19. While the requirements are not device- specific, they are certainly specific to manufacturing. Moreover, while the GMP regulations are written in necessarily broad language[22] to accommodate the myriad of different producers covered by the MDA, the GMP regulations create standards for almost every aspect of the manufacturing process. *See* 21 C.F.R. §§ 820.20-820.198. The FDA's forfeiture actions against non-complying manufacturers foreclose any suggestion that the GMP regulations are hortatory and without substantive effect. *See, e.g., United States v. Laerdal Manufacturing Corp.*, 853 F.Supp. 1219, 1222-23, 1227-35 (D.Or.1994); *United States v. Undetermined Quantities of Var. Articles*, 800 F.Supp. 499, 502-503 (S.D.Tex.1992); *United States v. 789 Cases*, 799 F.Supp. 1275, 1287-1293 (D.Puerto Rico 1992).

Appellants' negligent manufacturing claim constitutes a state requirement "different from, or in addition to" the GMP regulations' specific manufacturing requirements. We therefore hold that the district court properly granted summary judgment on this claim because it is preempted by the MDA.

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[22] For example, the regulation on personal sanitation within buildings states: Washing and toilet facilities shall be clean and adequate. Where special clothing requirements are necessary to assure that a device is fit for its intended use, clean dressing rooms shall be provided for personnel. 21 C.F.R. § 820.56(a).

3. Negligent Failure to Warn.

Appellants' complaint alleged that Appellee breached its duty of care to Lora Lohr by negligently failing to warn and instruct Ms. Lohr or her physicians about the dangers of the Activitrax pacemaker. The district court found that the MDA preempted this claim. A review of the MDA's warning and labeling requirements convinces us that the district court was correct.

Like their other negligence claims, Appellants' failure to warn claim could constitute a "State . . . requirement" and is preempted if the jury could conclude that a reasonable manufacturer's warnings and labels would be "different from, or in addition to" a specific MDA requirement. *See* 21 U.S.C.A. § 360k(a). Nothing in the MDA's 510(k) approval procedure, grandfathering provision, oversight and enforcement powers, or classification requirements constitute "specific requirements" justifying preemption under the Act. *See* 21 C.F.R. § 808.1(d). Like the manufacturing claim, however, Appellee points to additional MDA regulations governing labeling as specific requirements justifying preemption. *See* 21 C.F.R. §§ 801.109, 807.87(e).

Every prescription device like the Activitrax must comply with an MDA imposed labeling requirement. 21 C.F.R. § 801.109. The label on the device itself must inform the reader about the prescription-only nature of the device and the method of its application or use. 21 C.F.R. § 801.109(b). More importantly, labeling "on or within" the device's packaging must contain (1) usage information, "including indications, effects, routes, methods, and frequency and duration of administration," and (2) warning information, including any "relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c). The FDA screens the premarket submissions of all devices for compliance with la-

beling requirements, including 510(k) submissions. 21 C.F.R. § 807.87(e).

We believe these labeling requirements constitute specific requirements for preemption purposes. *Accord Michael*, 46 F.3d at 1324; *Reeves*, 44 F.3d at 305; *Mendes*, 18 F.3d at 18. As we have made clear, the labeling regulations' lack of device specificity does not dictate that they cannot be specific requirements for preemption purposes. Instead, the regulations are quite specific about what standards a manufacturer must follow when designing the packaging and labeling for its product. *See* 21 C.F.R. § 801.109(b), (c). As with the GMP regulations discussed above, the fact that the regulations are broadly phrased does not obviate their effectiveness, but rather reflects the need to encompass many thousands of devices within their requirements. Further, the FDA's record of taking action against mislabeled devices forecloses the argument that the Act's labeling requirements lack substantive "bite." *See, e.g.*, *United States v. Various Articles of Device*, 814 F.Supp. 32, 33 (E.D.Tenn.1992); *United States v. Articles of Device [Acuflex; Pro-Med]*, 426 F.Supp. 366, 370-71 (W.D.Penn. 1977).

Appellants' failure to warn claim constitutes a state requirement "different from, or in addition to" the MDA's specific labeling requirements. We therefore hold that the district court properly granted summary judgment on this claim because it is preempted by the MDA.

4. Strict Liability in Tort.

Appellants' complaint alleged that Appellee is strictly liable for Lora Lohr's injuries because it introduced an unreasonably dangerous product—the Activitrax—into the market. As with Appellants' other claims, the district court concluded that the MDA preempted this claim. A comparison of

Florida's strict liability law and the regulatory scheme applicable to the Activitrax convinces us that the district court was incorrect and that Appellants' strict liability claim, insofar as it alleges that the Activitrax and Model 4011 are unreasonably dangerous as designed, should be allowed to proceed.

Like Appellants' other claims, a Florida strict liability action could impose a "State ... requirement" on the Activitrax. 21 U.S.C.A. § 360k(a). A strict products liability action under Florida law would ask the jury "whether the [Activitrax] supplied by [Appellee] was defective when it left the possession of [Appellee]." Florida Standard Jury Instructions, § PL. The jury can find a product defective "if it is in a condition unreasonably dangerous to the user [and reaches] the user without substantial change" or "if by reason of its design the product is in a condition unreasonably dangerous to the user [and reaches] the user without substantial change." Florida Standard Jury Instructions, §§ PL 4, PL 5. A product may be unreasonably dangerous due to defects in its design, manufacture, or labeling. *See, e.g., Radiation Technology, Inc. v. Ware Const. Co.*, 445 So.2d 329, 331 (Fla.1983); *Brown v. Glade and Grove Supply, Inc.*, 647 So.2d 1033, 1035 (Fla.App.1994).

Under Florida's strict liability doctrine, the burden of rendering a product safe is placed in the hands of the entities "in a better position to ensure the safety of the products." *Samuel Friedland Family Enterprises v. Amoroso*, 630 So.2d 1067, 1068 (Fla.1993). A finding that defects in a product render it unreasonably dangerous is necessarily a finding that the product is unsafe. The word "dangerous" itself is defined in terms of safety: "exposing to danger, involving risk, demanding caution or care as extremely unsafe." Webster's New International Dictionary 573 (3d ed. 1976). Thus, if the MDA establishes specific requirements designed to avoid

having unsafe products reach users, then Appellants' strict liability action would be "different from, or in addition to" the MDA standard and is therefore preempted. *See* 21 U.S.C.A. § 360k(a).

Our analysis of Appellants' three negligence claims guides our strict liability inquiry. Because the 510(k) process, grandfathering provision, oversight and enforcement powers, and classification requirements do not impose specific safety requirements on the Activitrax's design, it follows that they do not prevent that design from creating an unreasonably dangerous product. In contrast, because the GMP and labeling requirements create standards of care for manufacturing and labeling drafted to ensure that devices are manufactured and labeled in a safe manner, it follows that these requirements should prevent the manufacturing or labeling of the Activitrax from creating an unreasonably dangerous product.[23]

Accordingly, we hold that Appellants' strict liability claim arising from an allegedly unreasonably dangerous design is not preempted, but any contentions that the manufacture or labeling of the Activitrax created an unreasonably dangerous product are preempted by the MDA. On remand, the district court should ensure that Appellants' strict liability claim is limited to proving that the Activitrax and Model 4011 lead are unreasonably dangerous as designed.

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[23] Preempting strict liability claims arising from some processes, but not others, is consistent with Florida caselaw. *See ISK Biotech Corp. v. Douberly*, 640 So.2d 85, 88-89 (Fla.App.1994) (preempting, under FIFRA, failure to warn claim but allowing strict liability claim "based solely on the product's defective condition" to proceed); *Brennan v. Dow Chemical Co.*, 613 So.2d 131, 132 (Fla.App.1993) (same).

Appellants should not be allowed to revive their preempted negligent manufacturing and failure to warn claims in the form of a strict liability claim.

III. CONCLUSION

The Court's decision to preempt some, but not all of Appellants' claims is sure to please neither party. Nevertheless, as the Supreme Court noted in a recent preemption decision, "[t]he middle course we adopt seems to us best calculated to carry out the congressional design." *Wolens*, — U.S. at ——, 115 S.Ct. at 827. Any displeasure with that design should be directed toward Congress. The lines and distinctions we draw in today's decision are not always neat or easy, but "in our system of adjudication, principles seldom can be settled 'on the basis of one or two cases, but require a closer working out.' " *Id.* (quoting Pound, Survey of the Conference Problems, 14 U.Cin.L.Rev. 324, 339 (1940)).

In conclusion, we hold that the district court properly held that Appellants' negligent manufacture and negligent failure to warn claims are preempted by the MDA. But the district court erred when it held Appellants' negligent design claim and strict liability claim arising from an unreasonably dangerous design were preempted by the Act.

AFFIRMED in part, REVERSED in part, and REMANDED.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Filed
March 16, 1994

LORA LOHR and MICHAEL LOHR,

Plaintiffs,

v. Case No. 93-482-Civ-J-20

MEDTRONIC, INC.,
a foreign corporation,

Defendant.

ORDER

Before the Court is Defendant's Motion for Reconsideration or Certification (Doc. No. 48, filed January 25, 1994). Plaintiffs responded in opposition on February 1, 1994 (Doc. No. 49).

On February 15, 1994, the Court directed the parties to submit supplemental memoranda addressing the applicability of the recently issued per curiam opinion in the consolidated cases *Duncan v. Iolab Corp.* and *Rogers v. Optical Radiation Corp.*, 12 F.3d 194 (llth Cir. 1994). In this opinion, dated January 24, 1994, the court of appeals followed the Seventh Circuit in holding that the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act of 1938 preempted the plaintiffs' state law claims for negligence, strict liability in tort, and breach of implied warranty.

Plaintiff contends that *Duncan* decision is distinguishable for the following reasons: (1) *Duncan* involved an intraocular lens, as opposed to the cardiac pacemaker lead at issue in the instant matter; (2) Plaintiff Lora Lohr never signed a consent form, unlike the plaintiff in *Duncan*; and (3) Congress never expected the FDA to grant an investigation-device exemption to the instant pacemaker leads, as the FDA had done with the lens in *Duncan*. Defendant contends that *Duncan* is analogous to the instant case and is controlling precedent.

The Court agrees with Defendant's assertion. The distinctions offered by Plaintiff, all purely factual, do not rebut the clear language of *Duncan*, in which the court of appeals made no attempt to distinguish between different products. The court simply held that section 360(k) of the Medical Device Amendments of 1976 ("the MDA") to the Food, Drug and Cosmetic Act of 1938 preempts state law claims for negligence, strict liability in tort, and breach of implied warranty. The pacemaker lead in the instant matter was specifically regulated under the MDA.

On December 17, 1993, when the Court issued its Order denying Defendant's Motion for Summary Judgment (Doc. No. 45), it was not clearly established within this circuit that claims such as those pled by Plaintiffs were preempted by the MDA. As *Duncan* explicitly sets forth that such claims *are* preempted, this Court must give effect to that decision, which is binding precedent.

Accordingly, the Motion to Reconsider (Doc. No. 48) is **GRANTED.** The Court's prior Order denying Defendant's Motion for Summary Judgment (Doc. No. 45) is VACATED, and Defendant's Motion for Summary Judgment hereby is **GRANTED.** Defendant's alternative Motion for Certification (Doc. No. 48) is **MOOTED.**

The Clerk is directed to: (1) enter Judgment on behalf of Defendant; (2) tax costs accordingly; and (3) close the file.

DONE AND ORDERED at Jacksonville, Florida, this 16th day of March, 1994.

/S/
HARVEY E. SCHLESINGER
United States District Judge

Copies to:

Robert F. Spohrer, Esq.
Robert L. Cowles, Esq.
David R. Tyrrell, Esq.

Garry Randolph

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Filed
Feb. 16, 1994

LORA LOHR and MICHAEL LOHR,

Plaintiffs,

v. Case No. 93-482-Civ-J-20

MEDTRONIC, INC.,
a foreign corporation,

Defendant.

ORDER

Before the Court is Defendant's Motion for Reconsideration or Certification (Doc. No. 48, filed January 25, 1994). Plaintiffs responded in opposition on February 1, 1994 (Doc. No. 49).

It appears to the Court that neither party may be aware of the issuance of a per curiam opinion by the Eleventh Circuit in *Duncan v. Iolab Corp.*, No. 92-2620 (consolidated with *Rogers v. Optical Radiation Corp.*, No. 92-2801). In this opinion, dated January 24, 1994, the court of appeals followed the Seventh Circuit in holding that the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act of 1938 preempted the plaintiffs' state law claims for negligence, strict liability in tort, and breach of implied warranty. The opinion was scheduled to issue as mandate on February 15, 1994.

The Court will defer ruling on Defendant's Motion until the parties have had an opportunity to comment on the applicability of this recent decision to the case at bar. Accordingly, on or before March 1, 1994, each party shall simultaneously file *brief* memoranda addressing the applicability of *Duncan* to the instant case.

DONE AND ORDERED at Jacksonville, Florida, this 15th day of February, 1994.

/S/
HARVEY E. SCHLESINGER
United States District Judge

Attachment
Copies to:

Robert F. Spohrer, Esq.
Robert L. Cowles, Esq.
David R. Tyrrell, Esq.

Law Clerk

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

Filed
Dec. 17, 1993

LORA LOHR and MICHAEL LOHR,

Plaintiffs,

v. Case No. 93-482-Civ-J-20

MEDTRONIC, INC.,
a foreign corporation,

Defendant.

ORDER

Before the Court is Defendant's Motion for Summary Judgment (Doc. No. 36, filed November 1, 1993). Plaintiffs filed a response in opposition on November 12, 1993 (Doc. No. 43).

Defendant is the manufacturer of an allegedly defective cardiac pacemaker lead which allegedly caused or contributed to injuries to Plaintiff Lora Lohr. Plaintiffs filed this action in state court, setting forth claims of negligence, strict liability and breach of warranty by Defendant, alleging, inter alia, that the pacemaker and the attached leads were made of defective materials and contained metallurgical defects. After the matter was removed to this Court, the claim for breach of warranty (Count III) was dismissed.

In the instant Motion, Defendant argues that its pacemaker device, the Medtronic Model 4011, has been approved

for sale and use by the Food and Drug Administration ("FDA"), and that such approval preempts any state cause of action such as is brought in the instant lawsuit. Plaintiffs contend in opposition that there is no federal preemption and, therefore, that their suit under state law should be allowed to proceed.

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories and admission on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the initial burden of showing the Court, by reference to materials on file that there are no genuine issues of material fact that should be decided at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Clark v. Coats & Clark, Inc.*, 929 F.2d 604 (11th Cir. 1991). A moving party discharges its burden on a motion for summary judgment by "showing" or "pointing out" to the Court that there is an absence of evidence to support the nonmoving party's case. *Celotex*, 477 U.S. at 325. Rule 56 permits the moving party to discharge its burden with or without supporting affidavits and to move for summary judgment on the case as a whole or on any claim. *Id.* When a moving party has discharged its burden, the nonmoving party must then "go beyond the pleadings," and by its own affidavits, or by "depositions, answers to interrogatories, and admissions on file," designate specific facts showing that there is a genuine issue for trial. *Id.* at 324.

In determining whether the moving party has met its burden of establishing that there is no genuine issue as to any material fact and that it is entitled to judgment as a matter of law, the Court must draw inferences from the evidence in the light most favorable to the nonmovant, *Key West Harbor v. City of Key West*, 987 F.2d 723, 726 (11th Cir. 1993), and re-

solve all reasonable doubts in that party's favor. *Spence v. Zimmerman*, 873 F.2d 256, 257 (11th Cir. 1989). The nonmovant need not be given the benefit of every inference, but only of every "reasonable" inference. *Brown v. City of Clewiston*, 848 F.2d 1534, 1540 n.12 (11th Cir. 1988). The Eleventh Circuit has explained the reasonableness standard:

> In deciding whether an inference is reasonable, the Court must "cull the universe of possible inferences from the facts established by weighing each against the abstract standard of reasonableness." [citation omitted]. The opposing party's inferences need not be more probable than those inferences in favor of the movant to create a factual dispute, so long as they reasonably may be drawn from the facts. When more than one inference reasonably can be drawn, it is for the trier of fact to determine the proper one.

WSB-TV v. Lee, 842 F.2d 1266, 1270 (11th Cir. 1988).

Thus, if a reasonable fact finder evaluating the evidence could draw more than one inference from the facts, and if that inference introduces a genuine issue of material fact, then the court should not grant the summary judgment motion. *Augusta Iron and Steel Works v. Employers Insurance of Wausau*, 835 F.2d 855, 856 (11th Cir. 1988). It must be emphasized that the mere existence of *some* alleged factual dispute will not defeat an otherwise properly supported summary judgment motion. Rather, "the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A dispute about a material fact is "genuine" if the "evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. The inquiry is "whether the evidence presents a sufficient disagreement to require submission to a

jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52.

The Court is not presently confronted with the existence of any "factual" disputes which might otherwise preclude entry of summary judgment. Rather, the Court must simply resolve the legal issue of whether the Plaintiffs' claims are preempted under the federal regulatory scheme. In any pre-emption analysis, the intent of Congress "is the ultimate touchstone." *Cipollone v. Liggett Group., Inc.*, 112 S. Ct. 2608, 2617 (1992) (citations omitted). Or, as stated in the same term *Cipollone* was decided:

> Pre-emption may be either expressed or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. Absent explicit pre-emptive language, we have recognized at least two types of implied pre-emption: field pre-emption, where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, and conflict pre-emption, where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the full purposes and objectives of Congress.

Gade v. National Solid Wastes Management Ass'n, 112 S. Ct. 2374, 2383 (1992) (citations and quotations omitted) (cited in *Public Health Trust v. Lake Aircraft*, 992 F.2d 291, 294 (llth Cir. 1993)). Thus, unless it is the "clear and manifest purpose of Congress" that state law be superseded, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), there is a strong presumption against federal preemption, *Cipollone*, 112 S. Ct. at 2617; *P.R. Consumer Affairs Dep't v. Isla Petroleum*, 485 U.S. 495, 500 (1988).

Upon review of the Motion, the Memorandum of Law submitted therewith, and the opposition filed thereto, the Court concludes that the instant matter is not federally pre-empted. The Court strongly concurs with Plaintiff that "regulation" does not equal "preemption." This is particularly true where, as here, the federal regulatory provision provides no cause of action or remedies for an allegedly defective product. Defendant's Model 4011 was approved by the FDA, and is subject to regulation by the Medical Device Amendment Act of 1976 ("MDA"). Florida law, which might provide relief to Plaintiffs should they ultimately prevail—the likelihood of which remains unknown—simply does not "stand[ ] as an obstacle to the full purposes and objectives of Congress." *Gade*, 112 S. Ct. at 2383.[1] Moreover, the Court notes that the basis of Plaintiffs' action is not the fact that this pacemaker was prescribed for use by the treating physician(s), but rather that the *manufacturer* did not conform to the federal regulations which Defendant believes preempt the action. While the federal government has approved the *use* of this and similar devices, the Court is not convinced that the government intended to take from Plaintiffs the opportunity to show that the product was defectively *manufactured*.

Accordingly, the Motion (Doc. No. 36) hereby is **DENIED.**

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[1] It would indeed be paradoxically unjust if the effect of federal *approval* and *regulation*—a scheme existing presumably to *prevent* or lessen the chance of product defects—would be to consistently bar mere access to the courts for (potential, if provable) relief from those defects.

DONE AND ORDERED at Jacksonville, Florida, this 17th day of December, 1993.

/S/
HARVEY E. SCHLESINGER
United States District Judge

Copies to:

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Robert L. Cowles, Esq.
David R. Tyrrell, Esq.

IN THE UNITED STATES COURT OF APPEAL
FOR THE ELEVENTH CIRCUIT

No. 94-2516

Filed
Aug. 15, 1995

LORA LOHR, MICHAEL LOHR, her husband,

Plaintiffs-Appellants,

versus

MEDTRONIC, INC., a foreign corporation,

Defendant-Appellee.

On Appeal from the United States District Court for the Middle District of Florida

---

ON PETITION(S) FOR REHEARING AND SUGGESTION(S) OF REHEARING EN BANC (Opinion _____, 11th Cir., 19 _, _____ F.2d _____).

Before: BLACK and BARKETT, Circuit Judges, and RONEY, Senior Circuit Judge.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no member of this panel nor other Judge in regular active service on the

Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure; Eleventh Circuit Rule 35-5), the Suggestion(s) of Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

/S/
UNITED STATES CIRCUIT JUDGE

21 U.S.C. § 360(k) (1994)

§ 360. Registration of producers of drugs or devices

. . . .

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

21 U.S.C. § 360k (1994)

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 C.F.R. § 807.81(a)(3) (1995)

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

. . . .

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

. . . .

21 C.F.R. § 807.87 (1995)

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all informa-

tion known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(k) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

21 C.F.R. § 808.1(d) (1995) (excerpt)

. . . .

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

. . . .

21 C.F.R. § 870.3680(b), (c) (1995)

§ 870.3680 Cardiovascular permanent or temporary pacemaker electrode.

. . . .

(b) Permanent pacemaker electrode—

(1) Identification. A permanent pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical

stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.

Supreme Court, U.S.
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(2)

No. 95-754

In The

Supreme Court of the United States

October Term, 1995

CORRECTED COPY

MEDTRONIC, INC.,

Petitioner,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Eleventh Circuit

RESPONSE TO PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state-law tort claims to recover for injuries caused by a defective medical device?

No. 95-754

In The

Supreme Court of the United States

October Term, 1995

MEDTRONIC, INC.,

Petitioner,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Eleventh Circuit

RESPONSE TO PETITION FOR A WRIT OF CERTIORARI

Respondents Lora Lohr and Michael Lohr hereby respond to the petition for a writ of certiorari filed by petitioner Medtronic, Inc. The petition seeks review of a ruling of the United States Court of Appeals for the Eleventh Circuit concerning injuries suffered by Ms. Lohr at the hands of petitioner's allegedly defective cardiac pacemaker lead. The court of appeals held that respondents' claims based on defective design of the medical device were not preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*

The issues presented in the petition have deeply divided the courts of appeals, as well as other federal and state courts. As the petition indicates, ten of the federal courts of appeals have addressed the question of MDA preemption,

and the prevailing situation is one of chaos. Thus, respondents agree with petitioner that review should be granted to resolve those issues and to provide clarity for the courts, medical device manufacturers, and consumers.

In addition, the court of appeals held that respondents' state-law claims based on an alleged breach of the common-law duty-to-warn and on manufacturing defects in petitioner's pacemaker lead were preempted by the MDA. The Eleventh Circuit's rulings on those claims are the subject of the Lohrs' cross-petition for a writ of certiorari, filed herewith. *See Lohr v. Medtronic, Inc.*, No. 95-___ (filed December 6, 1995). The cross-petition explains in detail that the deepening split among the circuits concerns legal issues that are present in all three claims ruled on by the Eleventh Circuit, and shows that a grant of certiorari on both the petition and the cross-petition will allow this Court to examine all of these issues, including the courts of appeals' divergent views on the proper interpretation of the Food and Drug Administration's MDA preemption regulations. *See* 21 C.F.R. § 808.1(d), *discussed in* cross-petition at 20-22. Further, granting both this petition and the cross-petition will afford respondents the opportunity to litigate their entire case, if the Court holds that none of their claims are preempted.

CONCLUSION

For the reasons stated above, and explained in detail in respondents' cross-petition, the petition for a writ of certiorari and the corresponding cross-petition for a writ of certiorari should be granted.

Respectfully submitted,

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Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

RULE 29.6 STATEMENT

Petitioner Medtronic, Inc. has no parent corporation and has no nonwholly owned subsidiaries.

TABLE OF CONTENTS

QUESTION PRESENTED i
RULE 29.6 STATEMENT ii
TABLE OF AUTHORITIES vi
OPINIONS BELOW 1
JURISDICTION 1
STATUTORY AND REGULATORY PROVISIONS INVOLVED 1
STATEMENT OF THE CASE 1
A. The Federal Statutory Framework 3
1. The Express Preemption Provision 4
2. FDA Authority to Ensure Safety and Effectiveness 5
a. Classification Requirements 5
b. Substantive Regulation and Enforcement Authority 6
c. Pre-Distribution Clearance Requirements 7
B. This Litigation 10
C. The Court of Appeals Opinion 11
INTRODUCTION AND SUMMARY OF ARGUMENT 12
ARGUMENT 16
THE FDCA PREEMPTS PLAINTIFFS' STATE COMMON LAW DESIGN CLAIMS 16

A. The FDCA Establishes Substantial Requirements Concerning the Design of the Model 4011 18

1. The 510(k) Requirements Empower the FDA to Authorize or Deny Marketing Clearance 19

a. Federal Requirements to Submit Information Justifying Premarket Clearance 22

b. Federal Requirements Governing the Substantial Equivalence Determination 23

2. The 510(k) Requirements Impose Substantial Restrictions on Changes in Device Design 27

3. The FDA Has Not Invoked Its Authority to Impose PMA Requirements 28

B. Federal Requirements Imposed Through the 510(k) Process Have Preemptive Effect 30

1. Federal Requirements Imposed Through the 510(k) Process Are "Applicable to the Device" 30

2. Federal Requirements Imposed Through the 510(k) Process Need Not Prescribe Particular Substantive Design Standards to Preempt State Requirements 32

C. The FDCA Preempts Plaintiffs' State Common Law Design Claims 36

1. Plaintiffs' Design Claims Would Establish State "Requirements" 36

2. Plaintiffs' Claims Would Allow a "State or Political Subdivision of a State" to "Establish or Continue in Effect" Requirements 40

3. Plaintiffs' Claims Would Establish State Requirements "With Respect to a Device Intended for Human Use" 41

4. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate[] to the Safety or Effectiveness of the Device or to Any Other Matter Included in a Requirement Applicable to the Device Under" the FDCA 41

a. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate[] to the Safety or Effectiveness of the Device" 41

b. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate To" Device Design, Which Is a "Matter Included in a Requirement Applicable to the Device" Under the FDCA 43

5. Plaintiffs' Design Claims Are Preempted, Because They Would Establish State Requirements "Different from, or in Addition to," Federal Requirements Applicable to the Model 4011 44

D. Preemption Is Consistent with Congress's Overall Design in the FDCA 46

CONCLUSION 49

TABLE OF AUTHORITIES

CASES	Page
American Airlines, Inc. v. *Wolens*, 115 S. Ct. 817 (1995)	42
Becker v. *Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995)	37
Chicago & Northwestern Transportation Co. v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981)	44,48
Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992)	11,14,17,37, 38,39,41,44
CSX Transportation, Inc. v. *Easterwood*, 507 U.S. 658 (1993)	18,33,39,40
Duncan v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994)	11
Duvall v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995)	28,37
Edmonson v. *Leesville Concrete Co.*, 500 U.S. 614 (1991)	40
English v. *General Electric Co.*, 496 U.S. 72 (1990)	46
Estate of Cowart v. *Nicklos Drilling Co.*, 505 U.S. 469 (1992)	31
Ex parte Virginia, 100 U.S. 339 (1880)	40
Freightliner Corp. v. *Myrick*, 115 S. Ct. 1483 (1995)	46
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TABLE OF AUTHORITIES continued

	Page
Gile v. *Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994)	37,39
Ingersoll-Rand Co. v. *McClendon*, 498 U.S. 133 (1990)	17,37
International Paper Co. v. *Ouellete*, 479 U.S. 481 (1987)	44
Kennedy v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995)	38
King v. *Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993)	37
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Martin v. *Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995)	38
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San Diego Building Trades Council v. *Garmon*, 359 U.S. 236 (1959)	37
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Stamps v. *Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993)	37

TABLE OF AUTHORITIES continued

Page

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United States v. *Park*, 421 U.S. 658 (1975) 7

Witt v. *Norfe, Inc.*, 725 F.2d 1277 (11th Cir. 1984) 42

CONSTITUTION AND STATUTES

U.S. Const. Art. VI, Cl. 2 16

Airline Deregulation Act of 1978 43

Employee Retirement Security Act of 1974 42

Federal Food, Drug, and Cosmetic Act,

21 U.S.C. 301-395 4

21 U.S.C. 331(a) 46

21 U.S.C. 331(b) 46

21 U.S.C. 331(c) 46

21 U.S.C. 331(k) 46

21 U.S.C. 331(*l*) 21

21 U.S.C. 331(p) 46

21 U.S.C. 331 (1982) 20

21 U.S.C. 332 7,46

21 U.S.C. 332 (1982) 20

21 U.S.C. 333 7,46

21 U.S.C. 333(g)(1)(A) 7

TABLE OF AUTHORITIES continued

Page

21 U.S.C. 333 (1982) 20

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21 U.S.C. 351(f)(2)(B)(i) 9,29

21 U.S.C. 352(o) 20,46

21 U.S.C. 352(o) (1982) 20

21 U.S.C. 360(k) 1,9

21 U.S.C. 360c 32

21 U.S.C. 360c(a)(1)(A) 6

21 U.S.C. 360c(a)(1)(B) 6

21 U.S.C. 360c(a)(1)(C) 6

21 U.S.C. 360c(a)(2)(C) 8

21 U.S.C. 360c(b)(1) ..... *passim*

21 U.S.C. 360c(f)(1) 23

21 U.S.C. 360c(f)(1)(A) 20

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21 U.S.C. 360c(i)(1)(A) 21,22

21 U.S.C. 360c(i)(1)(A)(i) 25

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21 U.S.C. 360d 32

21 U.S.C. 360e 32

TABLE OF AUTHORITIES continued

Page

21 U.S.C. 360e(a) 23
21 U.S.C. 360e(b) 9,10,29
21 U.S.C. 360e(b)(1) 8,29
21 U.S.C. 360e(c) 8
21 U.S.C. 360e(d) 8
21 U.S.C. 360h(a) 7
21 U.S.C. 360h(b) 7
21 U.S.C. 360h(e) 7
21 U.S.C. 360h(e)(1)(A) 7
21 U.S.C. 360h(e)(1)(B) 7
21 U.S.C. 360i 7
21 U.S.C. 360j(a) 32
21 U.S.C. 360j(g) 8,32
21 U.S.C. 360k 1,20
21 U.S.C. 360k(a) ..... *passim*
21 U.S.C. 360k(a)(1) 18
21 U.S.C. 360k(a)(2) 41
21 U.S.C. 360k(b) 5,49
21 U.S.C. 374 7
21 U.S.C. 381(a) 7

TABLE OF AUTHORITIES continued

Page

Public Health Cigarette Smoking Act of 1969,
15 U.S.C. 1331-1340 15,39,44
15 U.S.C. 1334(b) 38
28 U.S.C. 1254(1) 1
Illinois Consumer Fraud and Deceptive
Business Practices Act 43

REGULATIONS

21 C.F.R. Pt. 801 6
21 C.F.R. 807.39 21
21 C.F.R. 807.81(a) 20
21 C.F.R. 807.81(a)(3) 1
21 C.F.R. 807.81(a)(3)(i) 28,45
21 C.F.R. 807.87 1
21 C.F.R. 807.87(e) 23
21 C.F.R. 807.87(f) 23
21 C.F.R. 807.87(g) 28
21 C.F.R. 807.87(k) 23
21 C.F.R. 807.94 27
21 C.F.R. 807.97 21
21 C.F.R. 807.100(b)(2)(ii)(A) 25
21 C.F.R. 808.1(b) 39
21 C.F.R. 808.1(d) ..... *passim*

TABLE OF AUTHORITIES continued

Page

21 C.F.R. 808.55 5
21 C.F.R. 808.57 5
21 C.F.R. 808.61 5
21 C.F.R. 808.69 5
21 C.F.R. 808.71 5
21 C.F.R. 808.77 5
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21 C.F.R. 808.82 5
21 C.F.R. 808.85 5
21 C.F.R. 808.87 5
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21 C.F.R. 808.93 5
21 C.F.R. 808.97 5
21 C.F.R. 808.98 5
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21 C.F.R. Pt. 812 8
21 C.F.R. Pt. 814 8
21 C.F.R. Pt. 820 6
21 C.F.R. 860.84 6
21 C.F.R. Pts. 862-892 31
21 C.F.R. 870.3(a) 20

TABLE OF AUTHORITIES continued

Page

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42 Fed. Reg. 42,520 (Aug. 23, 1977) 28, 45
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S. Rep. No. 33, 94th Cong., 2d Sess. (1976) 3,4,47
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Interim Response to Citizen Petition, FDA Docket No. 94A-0388 (Sept. 11, 1995) 21

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-36a) is reported at 56 F.3d 1335 (11th Cir. 1995). The opinion of the district court granting summary judgment against plaintiffs (Pet. App. 1b-3b) is not reported.

JURISDICTION

The court of appeals entered judgment on July 3, 1995. Medtronic filed a timely petition for rehearing on July 24, 1995, which the court of appeals denied on August 15, 1995. Medtronic filed a timely petition for certiorari on November 13, 1995, and plaintiffs filed a conditional cross-petition for certiorari on December 6, 1995. Both petitions were granted on January 19, 1996. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The appendix to Medtronic's petition for certiorari sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. 360(k), 360k; 21 C.F.R. 807.81(a)(3), 807.87, 808.1(d) (excerpt), 870.3680(b), (c). Pet. App. 1f.

STATEMENT OF THE CASE

Medical devices enhance and prolong human life. Plaintiff Lora Lohr acknowledges in her complaint that she might not be alive today without a safe and effective cardiac pacemaker system. She is just one of the many thousands of Americans who benefit from device technologies that have existed for several decades.

Medical devices often incorporate sophisticated technology. Device innovation is an inexact science, and even the safest and most effective devices will not work perfectly at all times for all users. Because of that reality, there is an inevi-

table trade-off between promoting the availability of good devices—to provide their intended benefits—and protecting the public against unsafe and ineffective devices. Over-regulation, even if based on good intentions, has the potential to endanger human health by stifling innovation in new technologies and inhibiting the manufacture and distribution of existing beneficial devices. Under-regulation has the potential to compromise health by exposing the public to unsafe and ineffective devices.

Accordingly, Congress had to strike a number of balances when it adopted the present medical device regulatory structure. This case calls on the Court to define the choice Congress made in deciding *who* should regulate device design and *how*. Did Congress, recognizing the dangers of over-regulation by the states, leave design issues to federal experts, who may authorize or proscribe the marketing of particular designs and employ a variety of remedial tools to cope with any problems discovered after marketing begins? Conversely, did Congress fear under-regulation at the federal level, leaving in place tort claims that allow juries and judges in fifty states to determine, after the fact, whether a particular design authorized for marketing by the federal experts falls beneath a state law standard of care?

The precise question presented by Medtronic's petition is whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts plaintiffs' state common law claims alleging defects in the design of a medical device regulated by the Food and Drug Administration ("FDA"). The medical device at issue is Medtronic's Model 4011 cardiac pacemaker lead, which is an essential component of a pacemaker system implanted in the body to help maintain the natural pace of a patient's heartbeat. The lead is designed to transmit small electrical pulses to the ventricle of the heart from another part of the implanted system—a pacemaker pulse generator—and

return signals from the heart to that generator. (R1-37-Exh. 1, at 2.)[1]

The Eleventh Circuit held that the FDCA does not preempt plaintiffs' state design claims, even though the FDA had reviewed and affirmatively authorized the Model 4011 for marketing pursuant to the FDCA. Because this holding exposes Medtronic to liability under state law for alleged defects in a medical device design authorized by federal law, Medtronic asks this Court to reverse the Eleventh Circuit's ruling.

A. The Federal Statutory Framework

In 1976, Congress passed the Medical Device Amendments ("MDA") to the FDCA, establishing comprehensive federal regulation of medical devices for the first time. Congress recognized that medical devices "hold the promise of improving the health and longevity of the American people" and intended that the MDA would ensure public access to safe and effective devices. See S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1976).

Because of the simultaneous need to promote safe and effective devices and to protect the public against unsafe and ineffective ones, Congress enacted the MDA as "a balanced regulatory proposal." H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Although the statute endowed the FDA with broad new regulatory powers to guard the public from unsafe and ineffective devices, it also included provisions designed to protect innovations in device technology from being "stifled by unnecessary restrictions." *Ibid.* Congress was well

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[1] Record citations are to the volume, docket entry number, and page of the court of appeals record.

aware that this new regulatory scheme extended to potentially life-saving mechanisms: it sought to encourage research and development of "sophisticated, critically important medical devices." S. Rep. No. 33, *supra*, at 2.

1. The Express Preemption Provision

Congress had to choose whether to view state regulation as a useful supplement to its own safeguards against unsafe and ineffective devices, or as an unnecessary restriction that might impede its goal of promoting device innovation and availability. Congress expressed its choice in the following preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[2]

21 U.S.C. 360k(a). The House committee report for the MDA describes this preemption provision as a "general prohibition on non-Federal regulation," expressing a congressional intent for broad preemption of state law. H.R. Rep. No. 853, *supra*, at 45.

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[2] The applicable chapter is chapter 9 of Title 21, which encompasses the entire FDCA, 21 U.S.C. 301-395.

Congress did recognize, however, that "there are some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation." *Ibid.* Congress therefore included a provision authorizing states to apply for an exemption from preemption, which the FDA may grant through notice and comment rulemaking procedures. 21 U.S.C. 360k(b). The FDA may exempt a state requirement if it is more stringent than the corresponding federal requirement. The FDA also may grant an exemption if the state requirement is "required by compelling local conditions" and if compliance with the state requirement would not cause a violation of any applicable FDCA requirement. *Ibid.* To date, the FDA has granted exemptions requested by 15 states and the District of Columbia under this provision.[3]

2. FDA Authority to Ensure Safety and Effectiveness

a. Classification Requirements

In passing the MDA, Congress also granted the FDA "significant new authority . . . to assure the safety and effectiveness of medical devices," H.R. Rep. No. 853, *supra*, at 3, so that the life-enhancing benefits of device technologies sufficiently outweigh any risks. Cf. S. Rep. No. 33, *supra*, at 10. The MDA established a comprehensive regulatory structure that includes a classification scheme that

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[3] 21 C.F.R. 808.55 (California), 808.57 (Connecticut), 808.61 (Hawaii), 808.69 (Maine), 808.71 (Massachusetts), 808.77 (Nebraska), 808.80 (New Jersey), 808.81 (New Mexico), 808.82 (New York), 808.85 (Ohio), 808.87 (Oregon), 808.88 (Pennsylvania), 808.93 (Texas), 808.97 (Washington), 808.98 (West Virginia), 808.101 (District of Columbia).

distinguishes among devices based upon safety and effectiveness concerns. The FDA assigns devices to one of three classes through notice and comment rulemaking procedures. See 21 U.S.C. 360c(b)(1); 21 C.F.R. 860.84. That classification decision is based upon recommendations by a panel of experts qualified by training and experience to evaluate the safety and effectiveness of the device in question. 21 U.S.C. 360c(b)(1) and (2).

Class I devices include those the FDA believes pose no unreasonable health risks. See 21 U.S.C. 360c(a)(1)(A). Class II devices are those for which special controls may be necessary to assure safety and effectiveness. *Id.* § 360c(a)(1)(B). This case involves a device in Class III, which includes devices represented to be life-sustaining or life-supporting, or those presenting a potentially unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C).

b. Substantive Regulation and Enforcement Authority

The FDA is empowered to assure that all classes of devices on the market are reasonably safe and effective. The FDA promulgates substantive safety and effectiveness requirements ranging from labeling regulations (which establish federal standards for warnings about possible dangers and side effects of device use) to the good manufacturing practice ("GMP") regulations (which implement federal quality assurance standards for devices). 21 C.F.R. Pts. 801, 820. The requirements the FDA establishes by regulation complement other substantive safety and effectiveness requirements imposed by the statute.

Under the MDA, the FDA also has broad enforcement power to remove unsafe or ineffective devices from the market, impose sanctions for conduct that endangers public health, and prohibit that conduct in the future. The FDA uses

these enforcement powers to address conditions it detects through mandatory manufacturer reports of device malfunctions, serious injuries, and deaths, and through its comprehensive authority to inspect device establishments. See 21 U.S.C. 360i, 374. In administering the FDCA, the FDA has authority to detain devices in domestic commerce and (in concert with the Customs Service) upon import into the United States. 21 U.S.C. 334(g), 381(a). The FDA also can issue administrative cease-and-desist orders barring the distribution and use of devices that present substantial public health risks. *Id.* § 360h(e)(1)(A). In addition, the FDA can require notification of dangers a device poses to public health, *id.* § 360h(a), 360h(e)(1)(B), and can order the repair, replacement, or refund of the purchase price of a device that presents an unreasonable public health risk, *id.* § 360h(b). The FDA also can order the recall of a device, *id.* § 360h(e), or impose administrative civil penalties for violations of the statute and related regulations, see *id.* § 333(g)(1)(A). Furthermore, on behalf of the FDA, the Department of Justice enforces FDCA requirements with civil actions for seizure and injunction. See *id.* §§ 332, 334. The Department of Justice also brings criminal prosecutions under the FDCA, which provides for strict criminal liability to protect public health. See *id.* § 333; *United States* v. *Park*, 421 U.S. 658 (1975).

c. Pre-Distribution Clearance Requirements

The MDA also gave the FDA authority to prevent distribution of devices without the agency's prior review and clearance. Although the FDA does not do its own research and development to spawn new device technology, it does review innovations that others have generated, authorizing distribution only if statutory standards are satisfied. The statute directs the agency to apply balancing tests that allow

clearance if the benefits of device use sufficiently outweigh the risks. See, e.g., 21 U.S.C. 360c(a)(2)(C).

The FDA reviews devices under one of three clearance processes. *First*, the FDA regulates clinical experimentation with new devices through the investigational device exemption ("IDE") process. To obtain FDA approval for any clinical experiment involving significant risk to the subject, the sponsor must submit an IDE application containing detailed information about the device and a proposed experimental plan. The FDA then reviews and, if appropriate, approves the application, which authorizes distribution of the device solely for experimental use. See *id.* § 360j(g); 21 C.F.R. Pt. 812.

Second, the FDA evaluates some Class III devices under the "premarket approval" process before allowing marketing to the general public. This process applies to new technologies that are significantly different from devices already on the market and to additional Class III devices the FDA specifies by regulation. See 21 U.S.C. 360c(f)(1), 360e(b)(1). To obtain this authorization, the manufacturer submits a premarket approval application ("PMA") containing significant information about the device for FDA review. If clinical data and other information in the PMA demonstrate that the device's safety and effectiveness are reasonably assured, the FDA approves marketing. See *id.* § 360e(c), (d); 21 C.F.R. Pt. 814. The premarket approval process involves the most stringent regulatory review undertaken by the FDA. See Pet. App. 4a.

When Congress enacted the MDA, it could not impose PMA requirements on devices already on the market without immediately prohibiting distribution of a broad spectrum of valuable devices, thereby endangering those dependent on them. Under the MDA, Congress allowed marketing of these

"preamendment" devices to continue until the FDA could determine whether premarket approval was necessary to assure reasonable safety and effectiveness. See H.R. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990). Congress also maintained the availability of preamendment devices by prohibiting the FDA from imposing PMA requirements before manufacturers had sufficient time to assemble the data necessary to satisfy those requirements. The statute therefore bars the FDA from imposing PMA requirements until 30 months after it assigns a device to Class III. 21 U.S.C. 351(f)(2)(B)(i); see H.R. No. 853, *supra*, at 42. The statute did not, however, dictate when (after this 30-month period) the FDA *must* require PMAs for Class III preamendment devices. Accordingly, the FDA regulates Class III preamendment devices under the broad substantive requirements and enforcement powers described above until it decides to impose PMA requirements by regulation. See 21 U.S.C. 360e(b).

Third, if a "postamendment" Class III device such as the Model 4011 is not subject to PMA requirements, the statute requires premarket review and clearance through the "510(k)" process.[4] This process is established by, and named after, Section 510(k) of the FDCA, 21 U.S.C. 360(k), under which manufacturers submit information about the device, including its design, to the FDA to obtain marketing authorization. The FDA uses this information to determine whether the device under review is "substantially equivalent" to a preamendment device that the agency has allowed to be marketed without an approved PMA. The substantial equivalence

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[4] The FDA also clears postamendment devices in Class II, and some in Class I, for marketing under the 510(k) process.

determination establishes that the device under review and the preamendment device have comparable safety and effectiveness. See, e.g., H.R. Rep. No. 853, *supra*, at 36. The FDA authorizes marketing if the devices are substantially equivalent and denies clearance if they are not. If the FDA clears the Class III device under the 510(k) process and later determines that it should be reviewed under the premarket approval process, it issues a regulation requiring PMAs. See 21 U.S.C. 360e(b).

B. This Litigation

In 1982, Medtronic filed a 510(k) submission with the FDA seeking clearance to market the Model 4011. The FDA requested additional information relating to the device's design, including explanations regarding proposed materials and the lead's structure and function. (R1-37-Exh. 1, at 3.) Following receipt of this information, the FDA authorized the lead for marketing. *Ibid.*

Plaintiff Lora Lohr is wholly dependent upon pacemaker technology for the proper functioning of her heart, described by her physician as "100 percent paced." (R1-28-12.) Mrs. Lohr was implanted with a Model 4011 in 1987 at the age of 27. (See R1-3-1.) Approximately four years after the implant, the Model 4011 allegedly ceased functioning effectively, and Mrs. Lohr's physician replaced it with a different manufacturer's lead. (See R1-3-2.) The second lead in turn was replaced approximately two years later with the lead she depends upon today. (R1-28-32, 33.)

Mrs. Lohr and her husband subsequently filed this suit in Florida state court, asserting claims of negligence, strict liability, and breach of implied warranty concerning an alleged pacemaker system failure attributed to the Model 4011. The action was removed to the United States District Court for the Middle District of Florida as a diversity of citizenship case.

The district court subsequently dismissed the implied warranty claim for failure to state a claim under Florida law. See Pet. App. 6a-7a, 1d.

Medtronic then moved for summary judgment on the ground that the express preemption provision of the FDCA, 21 U.S.C. 360k(a), preempted the remaining negligence and strict liability claims. Although the district court initially denied the motion, Pet. App. 1d, it granted reconsideration because of the Eleventh Circuit's decision in *Duncan* v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994), which had affirmed the preemption of negligence and strict liability claims under the FDCA. The district court held that all of plaintiffs' claims were preempted and entered judgment for Medtronic. Pet. App. 1b.

C. The Court of Appeals Opinion

The Eleventh Circuit affirmed in part and reversed in part, holding that plaintiffs' claims alleging failure to warn and defective manufacture were preempted but that their defective design claims were not. The court based its analysis primarily upon the FDCA preemption provision and a comparison between state and federal requirements governing the Model 4011.

Citing this Court's opinion in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), the Eleventh Circuit held that common law actions were state "requirements" subject to preemption under Section 360k(a). See Pet. App. 11a. Specifically, the court of appeals held that plaintiffs' claims would create state "requirements" by asking a jury to determine how a reasonable manufacturer should design, manufacture, and provide warnings for the Model 4011. Pet. App. 25a, 30a, 32a.

The Eleventh Circuit then held that there are federal "requirements" within the language of Section 360k(a) that preempt plaintiffs' claims involving allegations of failure to warn and defective manufacture. However, the Eleventh Circuit also held that plaintiffs' claims relating to device design are not preempted, because the court could not identify any preemptive federal design "requirement" that met its construction of Section 360k(a). Pet. App. 28a-29a. The court suggested that there could be no express preemption of design claims unless there were substantive federal requirements that "set the standard" for the device's design. See Pet. App. 25a. Concluding that the FDCA does not specify such design standards, the court held that the plaintiffs' design claims are not expressly preempted. Pet. App. 29a. The Eleventh Circuit also held that the design claims are not impliedly preempted, because it could not identify an actual conflict between state and federal law. See Pet. App. 10a n.5. The Eleventh Circuit's holding therefore preserved certain claims from express and implied preemption even though they would expose Medtronic to state law liability for marketing a device design that the FDA had authorized under federal law.

INTRODUCTION AND SUMMARY OF ARGUMENT

The FDCA preempts plaintiffs' common law claims relating to the design of the Model 4011. The FDCA preemption provision prohibits state requirements relating to device safety and effectiveness or device design if they are "different from, or in addition to," any applicable federal requirement. Preemption analysis therefore entails identifying the federal and state requirements encompassed by the preemption provision and comparing them to determine whether the state requirements are different from, or in addition to, the federal requirements. If so, they are preempted.

I. The FDA's 510(k) premarket clearance process imposes a variety of "requirements" that trigger preemption under the FDCA. That process imposes two major types of federal requirements relating to the design and safety and effectiveness of the Model 4011. First, the FDCA establishes requirements that grant the FDA power to authorize marketing. These requirements include prohibitions on marketing without FDA clearance; submission requirements dictating the information about the device (including its design) the FDA will review; and the "substantial equivalence" requirement, which defines the devices the FDA may clear for marketing.

Second, after marketing begins, additional federal requirements prohibit changes in the FDA-authorized design that could significantly affect safety or effectiveness without further FDA clearance. These requirements effectively prevent the manufacturer from changing the design reviewed and cleared by the FDA.

The FDA has the power to impose a third possible type of requirement—PMA approval—on devices such as the Model 4011. The FDA has elected not to exercise that power for pacemaker leads, indicating that other safeguards are adequate to ensure their safety and effectiveness.

The preemption provision encompasses all of these federal 510(k) requirements. Under that provision, "*any*" federal requirement preempts defined categories of state requirements as long as it is "applicable to the device." The 510(k) requirements come within the plain meaning of this statutory language. In addition, two other FDCA sections use the same terminology, explicitly referring to Section 510 as imposing "requirements" that are "applicable to the device." Reading these sections together with the FDCA preemption provision

confirms that the 510(k) requirements preempt any state requirement that provision encompasses.

The Eleventh Circuit, however, held that the 510(k) requirements have *no* preemptive effect at all, because they do not dictate particular federal design standards on their face. This was error. The court of appeals bypassed the language of the FDCA preemption provision and premised its holding upon the FDA interpretative regulation set forth at 21 C.F.R. 808.1(d). The court instead should have applied the plain meaning of the statutory language. Furthermore, the regulation itself indicates that the 510(k) requirements are preemptive.

II. Plaintiffs' state common law claims also meet all of the statutory criteria requiring their preemption. The preemption provision applies to

(a) "*any requirement*"

(b) that a state or political subdivision "*establish*[*es*] *or continue*[*s*] *in effect*,"

(c) "*with respect to a device intended for human use*,"

(d) that "*relates* [i] *to the safety or effectiveness of the device or* [ii] *to any other matter included in a requirement applicable to the device*" under the FDCA, and

(e) that is "*different from, or in addition to*," "any" applicable FDCA "requirement" such as those imposed under Section 510(k).

(a) Under the statute's plain meaning, the duties imposed by plaintiffs' common law claims are state "requirements." Common law duties have as potent a regulatory effect as state legislative enactments, requiring manufacturers to modify conduct to avoid future liability. Furthermore, this Court's decision in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504

(1992), which held that common law claims were "requirements or prohibitions" preempted by the Public Health Cigarette Smoking Act of 1969, applies directly to this case. The language of the FDCA preemption provision is indistinguishable in relevant respects from the language of the statute at issue in *Cipollone*.

(b) Plaintiffs' common law design claims would allow a "state or political subdivision of a state" to "establish or continue in effect" state requirements. The requirements at issue are established by Florida state judges and juries, and they would continue in effect unless preempted.

(c) Plaintiffs' claims would establish state requirements "with respect to a device intended for human use." The ordinary meaning of the phrase "with respect to a device" applies to those claims, which allege that Medtronic should have marketed a device with a different design.

(d) The state law requirements that would be established by plaintiffs' claims "relate to the safety or effectiveness of the device." The duties underlying plaintiffs' claims relate fundamentally to both safety and effectiveness, because plaintiffs assert that the alleged failure of the device to continue operating properly endangered Mrs. Lohr. In addition, the state law requirements established by plaintiffs' claims would "relate to" device design, which is a "matter included in a requirement applicable to the device" under the FDCA.

(e) Plaintiffs' claims are preempted, because they would establish state requirements "different from, or in addition to," the federal 510(k) requirements. The premise of plaintiffs' claims is that Florida common law imposed a duty on Medtronic to market an allegedly safer and more effective device design than that cleared by the FDA under the 510(k) process. The 510(k) requirements therefore authorize marketing a device design that state law, through plaintiffs' claims,

would treat as defective. Furthermore, plaintiffs' claims would require Medtronic to change the device design in order to avoid future common law liability. The changes demanded by state law would conflict with federal 510(k) requirements barring design changes without FDA clearance. If Medtronic attempted to comply with the state law duty and immediately changed the design of the Model 4011, it would violate the federal 510(k) requirements and be subject to civil and criminal enforcement actions.

Beyond parsing of the statutory language, preemption is consistent with the purpose of the statute and sound public policy. Denying preemption would undermine Congress's decision that the responsibility for regulating device design falls within the FDA's expert judgment. Preservation of state design claims also would create a potential quagmire of inconsistent state requirements, often defined and imposed years after marketing clearance. Congress enacted the FDCA preemption provision for the purpose of prohibiting these restrictions, which Congress recognized could stifle innovation of new life-enhancing devices and interrupt continued nationwide availability of existing device therapies such as the one on which Mrs. Lohr depends. This Court therefore should reverse in part the judgment of the Eleventh Circuit and hold that the FDCA preempts plaintiffs' state common law design claims.

ARGUMENT

THE FDCA PREEMPTS PLAINTIFFS' STATE COMMON LAW DESIGN CLAIMS

The basis for federal preemption is the Supremacy Clause of the United States Constitution, which provides that "the Laws of the United States * * * shall be the supreme Law of the Land." U.S. Const. Art. VI, Cl. 2. Under that Clause, "state law that conflicts with federal law is 'without effect.' "

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981)). In any preemption analysis, "[t]he purpose of Congress is the ultimate touchstone." *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88, 96 (1992) (quoting *Malone* v. *White Motor Corp.*, 435 U.S. 497, 504 (1978)). Congress's intent to preempt state law "may be 'explicitly stated in the [federal] statute's language or implicitly contained in its structure and purpose.' " *Cipollone*, 505 U.S. at 516 (quoting *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Thus, "[t]o discern Congress' intent [a court should] examine the explicit statutory language and the structure and purpose of the statute." *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 138 (1990).

The language and structure of the FDCA express Congress's intent to preempt state common law claims relating to the design of Class III medical devices (such as the Model 4011) that the FDA has authorized for marketing under the 510(k) process. As explained below, the FDCA establishes a variety of "requirement[s] applicable to" the Model 4011 (including requirements relating to device design and safety and effectiveness). In addition, plaintiffs' common law design claims, if permitted to proceed, would "establish or continue in effect" state "requirements" that "relate[] to the safety or effectiveness of the device or to any other matter included in a [federal] requirement." And those state requirements would be "different from, or in addition to," the extensive federal requirements applicable to the Model 4011. The statute's exemption provision, moreover, provides further evidence that Congress intended broad preemption while vesting the FDA with authority to grant case-by-case exceptions. Finally, preemption of plaintiffs' design claims is fully consistent with Congress's objectives—it preserves incentives for manufacturers to bring new technologies onto the

market and continue improving existing devices but does not impair the FDA's broad authority to regulate device safety and effectiveness.

A. The FDCA Establishes Substantial Requirements Concerning the Design of the Model 4011

Preemption analysis begins with the plain wording of the statute, which "necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993), because it is assumed that the ordinary meaning of statutory language accurately expresses the legislative purpose. *Morales* v. *TWA, Inc.*, 504 U.S. 374, 383 (1992). The FDCA preemption provision's sweeping language states that "any requirement applicable under [the FDCA] to the device" preempts different or additional state requirements. 21 U.S.C. 360k(a)(1). The broad term "requirement" encompasses both federal statutory and regulatory provisions. Furthermore, *any* requirement under the FDCA is preemptive as long as it is "applicable to the device." In this case, the preemptive federal requirements are those imposed by the 510(k) process.

Despite the broad language of the statute, the Eleventh Circuit appears to have concluded that federal requirements must explicitly govern device safety to preempt plaintiffs' claims. The court of appeals denied preemption of the strict liability design claim because it believed that the 510(k) requirements, among others, did not "impose specific safety requirements" on the Model 4011. Pet. App. 35a. Similarly, holding that the 510(k) requirements did not preempt the negligent design claim, the court of appeals emphasized its belief that "[t]he 510(k) process is focused on equivalence, not safety." Pet. App. 27a.

The Eleventh Circuit's ruling is based on a misunderstanding of both the federal statute and the role played by the

FDA. The statute does not limit preemption to federal safety requirements: "*any*" FDCA requirement applicable to the device preempts additional or different state law. Furthermore, device safety is always implicated in the FDA's substantial equivalence determination. To envision the FDA as entirely agnostic on the question of the Model 4011's safety and effectiveness, as the Eleventh Circuit did, is quite wrong. The discussion below explains why the 510(k) requirements assure that the safety and effectiveness of the Model 4011 are comparable to a preamendment device.

The Eleventh Circuit also thought it pivotal that the MDA did not "establish[] specific requirements that apply to the design of" the device in question. Pet. App. 25a. Again the Eleventh Circuit was doubly wrong. The statute's plain language—"any requirement applicable * * * to the device"—is inconsistent with the conclusion that a "specific requirement[]" applicable "to the design" is necessary for preemption; and in any event, the 510(k) requirements actually are intimately related to device design, as the discussion below explains.

1. The 510(k) Requirements Empower the FDA to Authorize or Deny Marketing Clearance

The 510(k) requirements grant the FDA power to authorize or deny marketing of Class III devices such as the Model 4011. At the time the agency cleared the Model 4011, the FDCA prohibited manufacturers from marketing without filing a 510(k) submission seeking the FDA's permission; the agency had authority to seek civil and criminal sanctions

against manufacturers that violated this requirement.[5] The FDA also could initiate enforcement actions against manufacturers that marketed a device despite agency denial of 510(k) clearance.[6] Finally, if a 510(k) submission was pending at the FDA, the statute prohibited the manufacturer from marketing for 90 days unless the FDA granted clearance sooner.[7]

The FDA granted 510(k) clearance for the Model 4011 before this 90-day period expired, authorizing immediate marketing in a letter that stated:

> We have reviewed your premarket notification submission and have found the device to be substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. *You may, therefore, market your device* subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act).

(R1-37-Exh. A to Exh. 1) (emphasis added); see also 21 C.F.R. 870.3(a) (cardiovascular device that has been found

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[5] See 21 U.S.C. 352(o), 331-333 (1982); *United States* v. *An Article of Device*, 607 F. Supp. 990 (W.D. Mich. 1985) (seizure action premised upon failure to file 510(k) submission).

[6] The FDA denies clearance when it determines that the device under review is not "substantially equivalent" to a preamendment device. Devices that are not substantially equivalent are, by definition, Class III devices subject to PMA requirements. 21 U.S.C. 360c(f)(1)(A); 21 C.F.R. 870.3(b). Marketing a device without a required PMA renders it adulterated in violation of the FDCA. See 21 U.S.C. 351(f)(1)(B).

[7] 21 U.S.C. 360(k), 352(o); 21 C.F.R. 807.81(a).

substantially equivalent "may be commercially marketed" without an approved PMA).[8]

Even after it authorizes marketing, the FDA controls continued distribution of devices through the 510(k) requirements. The FDA consistently has taken the position that it has the authority to rescind 510(k) clearance. For example, under its fraud policy, the agency will rescind 510(k) clearance if there are fraudulent data in the submission documents. See 56 Fed. Reg. 46,191, 46,193, 46,197 (Sept. 10, 1991). Since 1988, the FDA has acted to rescind approximately seventy-five 510(k) clearances. Interim Response to Citizen Petition, FDA Docket No. 94A-0388 (Sept. 11, 1995). These rescission actions underscore the agency's broad authority to restrict market access under the 510(k) requirements.[9]

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[8] In the 1990 amendments to the FDCA, Congress added the requirement of an administrative order to the 510(k) clearance process. Since then, marketing is barred until the FDA "by order" has found substantial equivalence. 21 U.S.C. 360c(i)(1)(A). The legislative history of the 1990 amendments indicates that the addition of an administrative order was not intended to change the legal effect of the FDA's prior practice. S. Rep. No. 513, 101st Cong., 2d Sess. 19 (1990).

[9] Although the FDA affirmatively authorizes marketing through the 510(k) process, the agency also takes the position that 510(k) clearance does not denote official "approval" of the device. 21 C.F.R. 807.97. The FDA's position is consistent with other requirements in the statute and regulations barring manufacturers from advertising FDA status, even for PMA "approved" devices. The FDA's sensitivity is manifest in requirements barring representations that *either* 510(k) *or* PMA devices are "FDA-approved." Compare 21 C.F.R. 807.97 (representation that 510(k) clearance is FDA approval constitutes misbranding) with 21 U.S.C. 331(*l*) (representation in labeling or advertising that PMA device has premarket approval constitutes a prohibited act); see also 21 C.F.R. 807.39 (barring description of facility registration so as to connote

(Footnote cont'd on next page)

a. Federal Requirements to Submit Information Justifying Premarket Clearance

To obtain 510(k) clearance, manufacturers must comply with federal requirements to submit significant information about the device to the FDA. The manufacturer must provide all information the FDA deems necessary to determine substantial equivalence between the device under review and a preamendment or "predicate" device. Much of this information relates to device design, because the demonstration of substantial equivalence necessarily requires a comparison of the technological characteristics of the two devices. See 21 U.S.C. 360c(i)(1)(A). The information submitted also relates to safety and effectiveness, because the substantial equivalence determination requires a judgment relating to the devices' comparative safety and effectiveness. See pp. 23-27, *infra*.

Some information, such as proposed device labeling, is specifically required for all devices under 510(k) review. See 21 C.F.R. 807.87(e). Other information is required when the features of a particular device make it relevant to the substantial equivalence determination. This information may include photographs or engineering drawings, information regarding materials, design considerations, and energy used or

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approval). Particular terminology aside, the fact that 510(k) clearance is not characterized as an "approval" does not affect the preemptive force of the 510(k) requirements. The FDCA preemption provision draws no distinction between PMA and 510(k) devices, basing preemption on applicable federal "requirements" rather than on FDA "approval."

delivered by the device, and a description of its operational principles. *Id.* § 807.87(e), (f).

After it receives the 510(k) submission, the FDA may impose other requirements pursuant to 21 C.F.R. 807.87(k), which gives the agency authority to make specific requests for any additional data it deems relevant to the substantial equivalence determination. For example, after it received the 510(k) submission for the Model 4011, the FDA requested and received additional information concerning the lead's design (including explanations regarding proposed materials and the structure and function of the lead) before it would clear the device for marketing. (R1-37-Exh. 1, at 3.) An FDA request for additional information under Section 807.87(k) is a concrete requirement that must be complied with, because the agency deems the 510(k) submission withdrawn if the manufacturer does not honor the request within 30 days. *Id.* § 807.87(k).

b. Federal Requirements Governing the Substantial Equivalence Determination

After the FDA receives the information described above, it determines whether the device under review is substantially equivalent to a preamendment device. A device like the Model 4011 can be marketed only if the requirement of substantial equivalence is satisfied; absent substantial equivalence, the FDCA bars marketing without an approved PMA. See 21 U.S.C. 360c(f)(1), 360e(a).

The substantial equivalence determination is integrally related to the designs of the device under review and its preamendment predicate device and to the comparative safety and effectiveness of the two devices. At the time the FDA cleared the Model 4011 for marketing, the FDCA prescribed the substantial equivalence requirement without explicitly defining it. See 21 U.S.C. 360c(f)(1)(A) (1982). However,

the legislative history of the MDA indicates that Congress intended the substantial equivalence determination to ensure that devices marketed for the first time after its enactment are as safe and effective as preamendment devices. According to the House Report, devices are substantially equivalent if "differences between a new device and a marketed device do not relate to safety and effectiveness." H.R. Rep. No. 853, *supra*, at 36. The House Report also specifically indicates that differences in design are among the issues that can affect substantial equivalence. *Id.*

Consistent with Congress's mandate, the FDA has administered the 510(k) clearance process to ensure that the device under review (including its design) is as safe and effective as the predicate preamendment device. In 1983, shortly after it cleared the Model 4011 for marketing, the FDA described its substantial equivalence review process in an agency response to a GAO report as follows:

> We also believe FDA is applying the "substantial equivalency" test in a manner consistent with Congressional intent, though Congress' instructions are not explicit on the interpretation of this term. *FDA reviews premarket notifications to determine if the differences between pre- and post-Amendments devices are material to safety and effectiveness*. If there are no differences or if the differences do not present unanswered questions of safety and effectiveness, FDA finds post-Amendments devices "substantially equivalent" to their pre-Amendments predecessors. If the differences do present unanswered questions of safety and effectiveness, or if adequate comparisons cannot be made due to unique, new indications, then FDA finds post-Amendments devices "not substantially equivalent."

U.S. General Accounting Office, Pub. No. GAO/HRD-83-53, Federal Regulation of Medical Devices—Problems Still to Be Overcome 76 (Sept. 30, 1983) (emphasis added).

In 1990, Congress amended the FDCA to codify the FDA's long-standing interpretation of the term "substantial equivalence." See H.R. Rep. No. 808, 101st Cong., 2d Sess. 24 (1990); S. Rep. No. 513, 101st Cong., 2d Sess. 28 (1990). The 1990 amendments set forth two tests for substantial equivalence. The first refers explicitly to comparable safety and effectiveness, authorizing 510(k) clearance if a device with the same intended use as the predicate device (1) has different technological characteristics; (2) is as safe and effective as the predicate device; and (3) does not raise different questions of safety and effectiveness. See 21 U.S.C. 360c(i)(1)(A)(ii). Under this test, differences in technological characteristics relevant to the substantial equivalence determination include differences in device design. See 21 C.F.R. 807.100(b)(2)(ii)(A).

The second test authorizes 510(k) clearance if a device has the same intended use and technological characteristics as the predicate device. See 21 U.S.C. 360c(i)(1)(A)(i). This test also necessarily focuses on device design, which is the essential technological characteristic of any device. In addition, the second test assures comparable safety and effectiveness, although the statutory language does not explicitly refer to these factors. Read together with the requirements of the first test, the second test presumes that if the technological characteristics of two devices are the same, their safety and effectiveness will, by definition, be comparable. It is only if technological characteristics are different that comparable safety and effectiveness are uncertain.

The legislative history confirms this interpretation of the second test. The Senate Report for the 1990 amendments

states that a demonstration that devices have the same technologies is a demonstration that their safety and effectiveness is comparable:

> Generally speaking, a device is substantially equivalent to its predicate device if it has the same intended use, and is as safe and effective, as the predicate device. *The determination of comparable safety and effectiveness is at times easy, where the newer device and its predicate use the same technologies.* More difficult judgments occur when the technologies of the devices differ. In this latter situation, the FDA will not make a substantial equivalance [sic] determination without data, including clinical data, that demonstrates comparable safety and effectiveness.

S. Rep. No. 513, *supra*, at 28 (emphasis added).[10]

The FDA has confirmed since the 1990 amendments that its administration of the 510(k) clearance process *always* has required a finding of comparable safety and effectiveness:

> The legislative history of the 1990 amendments states Congress' express intent to codify FDA's interpretation of the term "substantial equivalence," including the agency's determination that *substantial equivalence requires a finding of comparable safety and effectiveness.*

59 Fed. Reg. 64,287, 64,288 (Dec. 14, 1994) (emphasis

[10] The Eleventh Circuit erroneously concluded that the substantial equivalence determination could be made without regard to safety and effectiveness if the technological characteristics of the two devices were the same. See Pet. App. 26a.

added) (citation omitted).[11]

The Eleventh Circuit therefore erred when it concluded that "while a substantial equivalence finding can be a finding of safety and effectiveness, there is no way to tell whether a given substantial equivalence finding is a finding of safety and effectiveness." Pet. App. 26a. Although it does not purport to guarantee safety and effectiveness, the 510(k) process ensures that new devices will be as safe and effective as their preamendment predicates.

2. The 510(k) Requirements Impose Substantial Restrictions on Changes in Device Design

The 510(k) premarket clearance only authorizes the marketing of a device with the particular design submitted to, and reviewed by, the FDA. Once a device is cleared for marketing through the 510(k) process, the manufacturer may not change the device design in a manner that could significantly affect safety or effectiveness without an additional 510(k) clearance by the FDA:

> A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process [requires filing a 510(k) submission seeking FDA clearance].

[11] Since the 1990 amendments, the FDA has promulgated new regulations expanding the safety and effectiveness information that must be included in 510(k) submissions for Class III devices. See, e.g., 21 C.F.R. 807.94 (requirement to include bibliography of safety and effectiveness data in 510(k) submission).

21 C.F.R. 807.81(a)(3)(i).[12] This prohibition on changes applies regardless of whether the manufacturer believes that they would decrease or increase device safety or effectiveness.[13] In *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), petition for cert. pending, No. 95-1010, the Fourth Circuit cogently explained the effect of these 510(k) requirements as follows:

> The FDA's determination that [the manufacturer's] prosthesis is substantially equivalent to those previously marketed thus binds [the manufacturer] to its representations to the FDA; for all intents and purposes, [the manufacturer] is required to continue to design, manufacture, and label the device as proposed in its original 510(k) Notification.

Id. at 399-400.

3. The FDA Has Not Invoked Its Authority to Impose PMA Requirements

Relying for premarket clearance on the 510(k) requirements described above, the FDA has not invoked its authority to bar marketing of the Model 4011 without PMA approval. The FDCA does give the FDA authority to impose PMA requirements for Class III devices, such as the Model 4011, previously cleared for marketing under the 510(k) process.

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[12] 21 C.F.R. 807.87(g) requires that the 510(k) submission relating to a proposed product change "must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device."

[13] See, e.g., 42 Fed. Reg. 42,520, 42,522 (Aug. 23, 1977) (preamble to 510(k) regulation).

When it decides to require this more extensive safety and effectiveness review, the FDA calls for PMAs by regulations that specifically describe the type of device that will be subject to premarket approval. See 21 U.S.C. 360e(b).[14] The statute dictates the timing of this FDA action, barring imposition of PMA requirements until 30 months after the agency assigns a device to Class III. 21 U.S.C. 351(f)(2)(B)(i). In its discretion, the FDA frequently has waited much longer than 30 months after classification to call for PMAs, regulating safety and effectiveness through the 510(k) process and its other broad powers until it decides that PMAs are necessary to assure reasonable safety and effectiveness. See, e.g., 60 Fed. Reg. 41,984 (Aug. 14, 1995). Although the FDA classified pacemaker leads such as the Model 4011 as Class III devices in 1980, it never has required PMAs for such products. See 21 C.F.R. 870.3680(b), (c).

The FDA's decision not to impose PMA requirements on the Model 4011 and other pacemaker leads indicates its apparent satisfaction with the degree of regulatory control the 510(k) requirements provide.[15] In fact, it appears the FDA

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[14] The regulation calling for PMAs applies both to the device cleared through the 510(k) process and to the preamendment predicate device. See 21 U.S.C. 360e(b)(1).

[15] It also appears that the FDA is satisfied regulating preamendment pacemaker leads without requiring PMA approval, because it has not exercised its authority to impose PMA requirements on those devices. The FDA regulates preamendment Class III devices under its substantive safety and effectiveness requirements and its broad enforcement powers to remove unsafe and ineffective devices from the market, retaining the authority to require PMAs if necessary. See pp. 8-9 *supra*. The Eleventh Circuit ignored these extensive requirements, using the term

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has concluded that PMAs may never be necessary to provide reasonable assurance of safety and effectiveness for the Model 4011 and other pacemaker leads. When it enacted the 1990 amendments, Congress imposed a timetable on the FDA for resolving whether to require PMAs for Class III devices. If the agency did not find PMA requirements necessary to provide reasonable assurance of safety and effectiveness, the amendments mandated it to propose reclassification to Class I or Class II, because devices in those classes, by definition, are never subject to PMA requirements. See 21 U.S.C. 360e(i)(2). Pursuant to this statutory mandate under the 1990 amendments, the FDA has indicated that there is a "high potential" that it will reclassify pacemaker leads to Class II, thereby barring future imposition of PMA requirements. 60 Fed. Reg. 41,986, 41,987-41,988 (Aug. 14, 1995) (notice regarding cardiovascular permanent pacemaker electrodes).

B. Federal Requirements Imposed Through the 510(k) Process Have Preemptive Effect

1. Federal Requirements Imposed Through the 510(k) Process Are "Applicable to the Device"

Section 360k(a) states that "*any* requirement applicable under this [Act] to the device" preempts certain defined state requirements. 21 U.S.C. 360k(a) (emphasis added). This plain language encompasses the federal 510(k) requirements imposed on the Model 4011. Those requirements "apply to"

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"grandfathering" pejoratively to suggest that preamendment devices entirely escape FDA safety and effectiveness regulation. See, e.g., Pet App. 4a, 5a.

devices such as the Model 4011, because they restrict marketable device designs to those that are substantially equivalent to preamendment devices, require FDA authorization for marketing the design, and then prohibit changes in the FDA-authorized design without further agency clearance.

The language of two other FDCA provisions confirms that Section 510(k) establishes federal "requirements" that are "applicable to" the device within the meaning of Section 360k(a). First, 21 U.S.C. 360c(d)(2)(A) authorizes the FDA to promulgate regulations that exempt certain Class I devices from 510(k) clearance and other federal requirements.[16] This provision establishes that Section 510 imposes "requirements" that are applicable to the device unless the FDA promulgates an exempting regulation that makes them "inapplicable." Section 360c(d)(2)(A) requires the FDA's exempting regulation to prescribe which of the "*requirements* of section [510] * * * shall *not apply to* the device." 21 U.S.C. 360c(d)(2)(A) (emphasis added). Under the same Section, a regulation that "makes a requirement of section [510] * * * inapplicable to a device" must be accompanied by an FDA explanation "for making such requirement inapplicable." Because identical terms in different sections of the same act are construed to have the same meaning, see, e.g., *Estate of Cowart* v. *Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992), Section 360c(d)(2)(A) confirms that the 510(k) process imposes "requirements" that are "applicable to the device" within the meaning of the FDCA preemption provision.

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[16] Under this statutory provision, the FDA has exempted over 500 Class I devices from the 510(k) process. See 21 C.F.R. Pts. 862-892.

Second, the language of 21 U.S.C. 360j(a) also confirms that the 510(k) process imposes federal "requirements" that are "applicable to the device." Under Section 360j(a), "[a]ny requirement authorized by or under section * * * [510] * * * applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed" by certain FDA actions. 21 U.S.C. 360j(a). Under the same Section, "any requirement established by or under section * * * [510] * * * which is inconsistent with" certain other federal requirements "shall not apply to the device." Section 360j(a) therefore unequivocally establishes that 510(k) requirements are "applicable to the device" unless the FDA changes their applicability or other statutory provisions not relevant to this case conflict with 510(k) requirements.[17] The language of Section 360j(a) therefore compels the conclusion that the 510(k) process establishes federal "requirements" that are "applicable to the device," and therefore are preemptive, under Section 360k(a).

2. Federal Requirements Imposed Through the 510(k) Process Need Not Prescribe Particular Substantive Design Standards to Preempt State Requirements

Despite the broad language of the FDCA preemption provision, the Eleventh Circuit held that plaintiffs' design

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[17] The particular FDA actions and requirements that may affect applicability of 510(k) requirements concern Sections 513, 514, 515, and 520(g) of the FDCA, 21 U.S.C. 360c, 360d, 360e, 360j(g). These FDCA Sections authorize the FDA to reclassify devices and adopt performance standards for Class II devices, premarket approval requirements for Class III devices, and IDE requirements for investigational devices. None of these provisions applies in this case.

claims were not preempted, because there were no federal requirements that "set the standard" for device design. See Pet. App. 25a. The court erred, because the statutory language provides no basis for limiting preemption to situations in which federal requirements dictate particular design standards. Under Section 360k(a), "any requirement" under the FDCA has preemptive effect if it is "applicable to the device."

The Eleventh Circuit's holding that there are no preemptive federal design requirements therefore is insupportable. The court of appeals explicitly acknowledged that it was rejecting a "literal reading of section 360k(a)," which it believed would raise a "host of problems" by inferring "broad preemptive intent." Pet. App. 16a. In doing so, the Eleventh Circuit refused to follow this Court's rulings to the effect that the plain wording of the statute "necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993).

Rather than relying on the ordinary meaning of Section 360k(a), the court of appeals found the following FDA interpretative regulation controlling:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. 808.1(d). Although it acknowledged that "a precise definition of what the FDA means by 'specific requirements' " is not possible, Pet. App. 21a, the Eleventh Circuit

relied on that phrase to conclude that there were no preemptive federal design requirements.

Even if it had been appropriate to bypass the express statutory language (which mandates preemption) in favor of this agency interpretation, the FDA's regulation does not, on its face, limit preemption of state-imposed design requirements in the manner claimed by the Eleventh Circuit. Although it adds the modifier "specific" (which is found nowhere in the statutory language) to the FDCA term "requirement," the FDA's regulation does not state that particular federal design standards are a prerequisite for preemption. Instead, the regulation indicates that as long as the "specific [federal] requirements" are "applicable to a particular device," they preempt state law. The analysis at pages 22-28 *supra* demonstrates that the 510(k) process unquestionably imposes specific design requirements that are applicable to the particular pacemaker lead at issue in this case. Therefore, construed consistently with the FDCA preemption provision, the FDA's interpretative regulation compels the conclusion that these specific federal design requirements have preemptive effect.

The errors in the Eleventh Circuit's analysis are made evident by the astounding effects its ruling would have. The holding would deny preemption of virtually all state design requirements applicable to Class III 510(k) devices, regardless of whether they were imposed through common law claims or legislative enactments. As a result, state legislatures and regulators could enact their own design standards, even if they conflicted with the particular device designs the FDA authorized for marketing. Furthermore, juries could conclude that it is "negligent" or otherwise in violation of state common law to use the federally authorized design.

For example, under the Eleventh Circuit's holding, states could prohibit (or juries could deem "negligent") the use of particular materials in the design of pacemaker leads, even though the FDA authorized marketing of leads designed with those materials. To make matters worse, different states, through legislation or common law decisionmaking, could adopt contradictory design standards, with some requiring use of the very same materials that others prohibited. It would be wholly inconsistent with the statutory language and congressional intent for the FDCA to preserve state design requirements that would impose conflicting standards or bar a manufacturer from marketing a design authorized under federal law.

Furthermore, if the 510(k) requirements were not preemptive, the states could impose different design requirements through their own premarket clearance processes. For example, state legislatures could adopt less restrictive versions of the federal 510(k) requirements, authorizing marketing of device designs that the federal requirements would prohibit. Conversely, states could enact statutes barring marketing of all Class III devices unless their designs had been approved through a state PMA process. These statutes would conflict directly with federal 510(k) requirements, which authorize marketing of some Class III devices (including the Model 4011) without an approved PMA. The FDCA preemption provision obviously is intended to bar these types of inconsistent state requirements.[18] This Court therefore should

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[18] The House Committee report for the MDA explicitly notes that a California statute establishing state PMA requirements was preempted unless and until the FDA granted an exemption from preemption. H.R. Rep. No. 853, 94th Cong., 2d Sess. 45-46 (1976).

reject the Eleventh Circuit's holding and conclude that the 510(k) process imposes federal design "requirements" within the meaning of the FDCA preemption provision.

C. The FDCA Preempts Plaintiffs' State Common Law Design Claims

Plaintiffs' state common law claims meet all of the statutory criteria requiring their preemption. The preemption provision applies to

(a) "*any requirement*"

(b) that a state or political subdivision "*establish*[*es*] *or continue*[*s*] *in effect*,"

(c) "*with respect to a device intended for human use*,"

(d) that "*relates* [i] *to the safety or effectiveness of the device or* [ii] *to any other matter included in a requirement applicable to the device*" under the FDCA, and

(e) that is "*different from, or in addition to*," "any" applicable FDCA "requirement" such as those imposed under Section 510(k). See 21 U.S.C. 360k(a) (emphasis added).

The analysis below explains why plaintiffs' state common law claims fall comfortably within each of these phrases.

1. Plaintiffs' Design Claims Would Establish State "Requirements"

Plaintiffs' common law design claims would establish state "requirements" within the meaning of Section 360k(a). Plaintiff's claims are premised upon the theory that Florida common law required Medtronic to provide a different design, allegedly safer and more effective, than the one cleared for marketing under the 510(k) process. Just as a state statute or regulation could mandate a different design, plaintiffs'

claims invoke the coercive power of the State of Florida to impose substantive design requirements.

In *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 522 (1992), a plurality of this Court explained that common law damages actions "are premised on the existence of a legal duty," and that "it is the essence of the common-law to enforce duties." This Court also has recognized that by imposing legal duties, common law claims assert regulatory obligations under state law that are as potent as a positive state enactment:

> [State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.

San Diego Bldg. Trades Council v. *Garmon*, 359 U.S. 236, 247 (1959); see also *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 142 (1990) (state common law claims could require "the tailoring of [pension] plans and employer conduct to the peculiarities of the law of each jurisdiction"). The plain meaning of the FDCA phrase "any requirement" easily encompasses the state law duties imposed by plaintiffs' design claims.[19]

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[19] The court below and eight other circuits have concluded that the FDCA preempts common law claims. *Lohr*, Pet. App. at 11a; *King* v. *Collagen Corp.*, 983 F.2d 1130 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993); *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995); *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994); *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), petition for cert. pending, No. 95-1010; *Stamps* v. *Collagen Corp.*, 984 F.2d 1416 (5th Cir.), cert. denied, 114 S. Ct. 86 (1993);

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Furthermore, this Court recently ruled that statutory language substantially identical to the FDCA preemption provision encompasses state common law claims. In *Cipollone*, the Court construed the following express preemption provision in the Public Health Cigarette Smoking Act of 1969:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

15 U.S.C. 1334(b). Six Justices concluded that the term "requirement or prohibition" in this provision encompassed state common law claims. 505 U.S. at 521-22 (opinion of Stevens, J.); *id.* at 548-49 (opinion of Scalia, J.). The plurality opinion of Justice Stevens explained the holding as follows:

> [Petitioner] argues that common-law damages actions do not impose "requirement[s] or prohibition[s]" and that Congress intended only to trump "state statute[s], injunction[s], or executive pronouncement[s]." We disagree; such an analysis is at odds both with the plain words of the 1969 Act and with the general understanding of common-law damages actions. *The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common*

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Martin v. *Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995); *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), cert. denied, 505 U.S. 917 (1992); *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), cert. denied, 115 S. Ct. 2614 (1995). But see *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995).

> *law; to the contrary, those words easily encompass obligations that take the form of common-law rules.*

Id. at 521 (emphasis added) (footnote omitted); cf. *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993) (state common law claims encompassed by preemption provision barring state "law, rule, regulation, order, or standard relating to railroad safety").

The *Cipollone* holding applies directly to this case, because the FDCA preemption language is in relevant respects "indistinguishable from the act at issue in *Cipollone*." *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 543 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994). The FDCA preempts state "requirement[s]," and the 1969 Cigarette Act construed in *Cipollone* preempts state "requirement[s] or prohibition[s]." The language differences between the two statutes are not material, because both phrases are properly interpreted as referring to the same legal duties. Given the holding in *Cipollone*, the conclusion is inescapable that state common law claims are "requirements" within the meaning of the FDCA preemption provision.[20]

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[20] Although reference to agency interpretations is unnecessary when, as in this case, the statutory language is clear, a portion of the FDA's interpretative regulation is consistent with the statutory language encompassing preemption of common law claims. According to the regulation, the FDCA preemption provision "prescribes a general rule" preempting certain defined state requirements "(whether established by statute, ordinance, regulation, or *court decision*)." 21 C.F.R. 808.1(b) (emphasis added).

2. Plaintiffs' Claims Would Allow a "State or Political Subdivision of a State" to "Establish or Continue in Effect" Requirements

The FDCA preemption provision also applies to plaintiffs' claims, because they would allow a "State or political subdivision of a State" to "establish or continue in effect" requirements through those claims. On its face, the term "State or political subdivision of a State" includes all organs of state government, including the judicial branch. See, e.g., *Ex parte Virginia*, 100 U.S. 339, 347 (1880) ("A State acts by its legislative, its executive, or its judicial authorities."); *Edmonson* v. *Leesville Concrete Co.*, 500 U.S. 614, 624 (1991) (jury is "quintessential governmental body"). Because the requirements plaintiffs seek to impose on Medtronic would be established by Florida state judges and juries, they come within the FDCA preemption provision.

Furthermore, the phrase "establish or continue in effect" is terminology wholly consistent with common law claims. These claims would enable Florida judges and juries to "establish" duties regarding design by requiring Medtronic to market a different design than the one authorized by the 510(k) process. In addition, consistent with the statute's plain meaning, those requirements would be "continue[d] in effect" through plaintiffs' claims unless preempted by the FDCA.

In *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658 (1993), this Court affirmed preemption of certain state common law claims, because the applicable preemption provision barred "[a] State" from "adopt[ing] or continu[ing] in force" certain railroad safety standards. *Id.* at 662 & n.2. The FDCA language is indistinguishable in relevant respects from that of the statute in *Easterwood*, and this Court similarly should construe it to bar plaintiffs' common law claims.

3. Plaintiffs' Claims Would Establish State Requirements "With Respect to a Device Intended for Human Use"

The FDCA preemption provision also applies to plaintiffs' common law claims, because they would establish state requirements "with respect to a device intended for human use." The ordinary meaning of the phrase "witn respect to a device" clearly applies to those claims, which allege that Medtronic should be required to market a medical device with a different design. Pacemaker leads are "intended for human use" and were so used in this case. Just as common law claims "with respect to" advertising and promotion of cigarettes were preempted in *Cipollone*, 504 U.S. at 524 (opinion of Stevens, J.); *id.* at 544 (opinion of Scalia, J.), plaintiffs' claims come within the FDCA preemption provision.

4. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate[] to the Safety or Effectiveness of the Device or to Any Other Matter Included in a Requirement Applicable to the Device Under" the FDCA

Subsection (2) of Section 360k(a) states a disjunctive test for the subjects a state "requirement" must "relate to" before it will be preempted. Plaintiffs' claims are preempted under either prong of that test.

a. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate[] to the Safety or Effectiveness of the Device"

Without question, plaintiffs' common law design claims "relate to the safety or effectiveness of the device" within the plain meaning of the FDCA preemption provision. Plaintiffs' design claims are premised upon the assertion that the Model

4011 design was not sufficiently safe or effective. Plaintiffs' negligent design claim asserts violation of a Florida common law duty to design the device with reasonable care, so that the device would be reasonably safe for use in a foreseeable manner. See, e.g., *Witt* v. *Norfe, Inc.*, 725 F.2d 1277, 1278 (11th Cir. 1984). Plaintiffs' strict liability claim asserts violation of a Florida duty to design the device so that it was not in a defective condition unreasonably dangerous to foreseeable users and bystanders when it left the manufacturer. See *id.* The duties underlying the claims obviously relate fundamentally to both safety and effectiveness, because plaintiffs assert that the alleged failure of the device to continue operating properly endangered Mrs. Lohr. See Conditional Cross-Petition for a Writ of Certiorari at 3.

This Court's recent decisions construing other express preemption provisions confirm that the FDCA language encompasses plaintiffs' claims. Interpreting the express preemption provision of the Employee Retirement Income Security Act of 1974 ("ERISA"), the Court has held that a state law "relates to" an employee benefit plan "if it has a connection with or reference to such plan." *Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983). Similarly, the Court has construed the term "relating to" in the express preemption provision of the Airline Deregulation Act of 1978 ("ADA") to mean "having a connection with, or reference to, airline 'rates, routes, or services.' " *Morales* v. *TWA, Inc.*, 374, 384 (1992). Using these decisions as a guide, plaintiffs' common law claims are preempted, because they would establish requirements having a connection with or reference to the safety or effectiveness of the Medtronic device.

Furthermore, in *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817, 823 (1995), this Court confirmed that a state requirement can "relate to" a particular subject matter for purposes of preemption without relating to that subject matter

exclusively. Thus, the Court held that claims asserted under the Illinois Consumer Fraud and Deceptive Business Practices Act were preempted by the ADA as "relating to" airline rates, routes, or services, even though the Illinois statute did not relate exclusively to (or even explicitly mention) those matters. Similarly, the common law doctrines invoked by plaintiffs "relate to" safety or effectiveness in this case, and they are preempted by the FDCA.

b. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate To" Device Design, Which Is a "Matter Included in a Requirement Applicable to the Device" Under the FDCA

It also is indisputable that plaintiffs' claims "relate to" the design of the Model 4011. Those claims have a connection with or reference to device design, because they allege breach of common law duties concerning design.

Claims "relating to" device design are within the FDCA preemption provision. Device design is a "matter included in a requirement applicable to the device" under the FDCA. As discussed at pages 22-28 *supra*, device design is a "matter included in" the 510(k) requirements. Furthermore, the discussion at pages 30-32 *supra* confirms that the 510(k) requirements are "applicable to the device." Plaintiffs' design claims therefore fall squarely within the FDCA preemption provision.

5. Plaintiffs' Design Claims Are Preempted, Because They Would Establish State Requirements "Different from, or in Addition to," Federal Requirements Applicable to the Model 4011

This Court should conclude that plaintiffs' design claims are preempted. Otherwise, they would establish state requirements "different from, or in addition to," the federal requirements imposed by the 510(k) process. The premise of plaintiffs' claims is that the design of the Model 4011 the FDA authorized for marketing violates Florida common law duties. As a result, federal law authorizes marketing of a design that state law, if plaintiffs' claims succeed, would treat as defective. Because the state law requirements are "different from, or in addition to," the federal 510(k) requirements that authorized marketing of the existing design, plaintiffs' claims are preempted. Cf. *Cipollone*, 505 U.S. at 524 (failure to warn claims preempted because they would require "additional, or more clearly stated, warnings" than those required under 1969 Cigarette Act) (Stevens, J.).

Furthermore, plaintiffs' claims are preempted, because they would require Medtronic to change the Model 4011 design authorized by the FDA under federal law. Plaintiffs' claims are premised upon a Florida law duty to use a design for the Model 4011 different from the one the FDA authorized for marketing under federal law through the 510(k) process. Cf. *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 495 (1987) (common law nuisance action would compel company to "adopt different control standards and a different compliance schedule from those approved by the EPA"); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981) ("threat of damages" from common law claims would "require a carrier to do exactly what the [Interstate Commerce] Commission is empowered to ex-

cuse"). Plaintiffs' claims therefore would impose state law design requirements "different from, or in addition to," the 510(k) requirements authorizing marketing of the Medtronic design.

The implications of allowing states to superimpose different or additional requirements on the Model 4011 come into sharp focus if Medtronic were to attempt to conform to the state law requirements established through plaintiffs' claims and immediately change the device design. Under these circumstances, Medtronic would violate the federal regulation restricting design changes in devices previously authorized for marketing under the 510(k) process. As explained above, 21 C.F.R. 807.81(a)(3)(i) bars design changes in a marketed device that could significantly affect safety or effectiveness without an additional 510(k) clearance.[21] In contrast, the state law requirements to be imposed by plaintiffs' claims *by definition* assert that the design should have been significantly safer or more effective. As a result, the design changes demanded by state law would be illegal under federal law absent FDA clearance. If Medtronic changed the

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[21] In administering the FDCA, the FDA consistently has taken the position that product changes require 510(k) clearance even though the manufacturer believes they would *increase* device safety or effectiveness. See, e.g., 42 Fed. Reg. 42,520, 42,522 (Aug. 23, 1977) (preamble to 510(k) regulation). Because the FDA's decisions on 510(k) submissions are committed to the agency's discretion, there is no assurance that the FDA would authorize any changes that Medtronic proposed, even if plaintiffs believed they would enhance device safety. The agency experts may not, for example, agree that the proposed change is safe. In any event, unless and until the FDA *did* authorize such changes, there can be no doubt that Medtronic's duties under state law would be "different from, and in addition to," federal requirements.

design without receiving clearance, its failure to comply with the FDA's 510(k) requirements would render the Model 4011 misbranded under the FDCA,[22] and subject Medtronic to civil and criminal enforcement actions.[23] Under these circumstances, plaintiffs' claims unquestionably would establish state requirements "different from, or in addition to," federal requirements applicable to the device. To make Medtronic choose between compliance with state law requiring design changes and federal law prohibiting them would produce a result wholly inconsistent with the FDCA preemption provision and Supremacy Clause jurisprudence.[24]

D. Preemption Is Consistent with Congress's Overall Design in the FDCA

The words Congress chose in the preemption provision—the best evidence of congressional intent—leave little room to argue that plaintiffs' design claims escape

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[22] See 21 U.S.C. 352(o).

[23] 21 U.S.C. 331(a)-(c), (k), (p), 332-334.

[24] Because the FDCA preempts state requirements whether they are "different from" or "in addition to" federal requirements, there need not be a direct conflict between federal and state law for the express preemption clause to apply. Nonetheless, in this case, there is a direct conflict; the state claims would impose liability for acts authorized under federal law, and the acts required by state law would cause federal violations. Given this conflict, plaintiffs' claims would be impliedly preempted even if this Court were to conclude that plaintiffs' claims were not expressly preempted. See, e.g., *English* v. *General Elec. Co.*, 496 U.S. 72, 79 (1990) (state law is impliedly preempted if it is "impossible for a private party to comply with both state and federal requirements"); *Freightliner Corp.* v. *Myrick*, 115 S. Ct. 1483, 1488 (1995) (existence of an express preemption provision does not foreclose implied preemption arising from actual conflict between federal and state law).

preemption. A brief reflection about the overall design and purposes of the FDCA confirms that the result mandated by the language is sensible and comports with the balance Congress struck among competing interests.

Congress undoubtedly was sensitive to the pain and suffering that can be inflicted by unsafe or ineffective medical devices. But it is just as clear—and pointedly evident in the legislative history of the MDA—that Congress was concerned about the human suffering that will go unremedied if medical devices are removed from, or never introduced to, the market because excessive or variant regulation or substantial regulatory uncertainty inhibits the needed innovation. See S. Rep. No. 33, *supra*, at 2 (Congress sought to encourage research and development of "sophisticated, critically important medical devices").

Common law tort liability is the least predictable form of regulation, and among the most burdensome. Compensation of injured persons is a worthy goal, but the current tort system comes with a price. Decisions are made by juries and judges who lack training in such fields as medical device design, manufacture, and use. Each decision is made after the fact, on an individual basis, and each claim (as the Eleventh Circuit recognized) "would ask the jury to declare what constitutes a reasonable design." Pet. App. 25a. Nor is there any way to ensure that one jury's "finding of fact" on that issue is consistent with any other jury's finding. There is no consistency from state to state even in defining the *general* standards that a device manufacturer is supposed to comply with in order to escape liability; toleration of state variety, a virtue of federalism in some contexts, comes with the price of allowing different states to impose different standards of liability.

In 1976, Congress chose what it believed to be a better way to regulate medical devices. It concluded that the FDA, working with panels of experts, and with the ability to consider *all* the costs, benefits, and risks of a particular design, could make more accurate decisions about "what constitutes a reasonable design" (Pet. App. 25a) than could a lay jury confronted only with the facts of one particular case and aided only by the testimony of the parties' chosen expert witnesses. Furthermore, by concentrating regulation at the federal level, Congress believed that it could minimize uncertainty, promote uniformity, and spur innovation that would not be "stifled by unnecessary restrictions." H.R. Rep. No. 853, *supra*, at 12; cf. *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981) ("A system under which each State could, through its courts, impose on railroad carriers its own version of reasonable service requirements could hardly be more at odds with the uniformity contemplated by Congress in enacting the Interstate Commerce Act.").

There admittedly are some costs associated with preempting state common law. Nonetheless, Congress was willing to accept those costs in order to have a regulatory system that would best serve the *many* persons who benefit from a medical device industry that is carefully regulated at the federal level by experts and not hamstrung by a patchwork of state requirements that are superimposed on the federal requirements. Because the scheme Congress chose has provided companies like Medtronic with a regulatory environment conducive to innovation, thousands of persons—including Mrs. Lohr herself—continue to benefit from life-enhancing device technology.

Congress was willing to see *some* supplementation of federal requirements, but not—as plaintiffs and the Eleventh Circuit contend—by tolerating common law design claims

such as Mrs. Lohr's. Instead, the process for supplementing federal requirements with state requirements is the exemption process under 21 U.S.C. 360k(b). It was the intent of Congress that unless the FDA has granted an exemption from preemption, state requirements fall within the "general prohibition on non-Federal regulation." H.R. Rep. No. 853, *supra*, at 45. This Court should honor that congressional intent and hold that the common law design claims at issue in this case are preempted.

CONCLUSION

The Court should reverse in part the judgment of the Eleventh Circuit and hold that the Federal Food, Drug, and Cosmetic Act preempts plaintiffs' negligence and strict liability claims regarding the design of the Medtronic Model 4011 cardiac pacemaker lead.

Respectfully submitted,

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Nos. 95-754, 95-886

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MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,
Respondent/Cross-Petitioners.

On Writ of Certiorari
to the United States Court of Appeals
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QUESTION PRESENTED

Do the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state-law tort claims to recover money damages for injuries caused by a defective medical device?

TABLE OF CONTENTS

QUESTION PRESENTED i

TABLE OF AUTHORITIES iv

OPINIONS BELOW 1

JURISDICTION 1

STATUTES AND REGULATIONS INVOLVED 2

STATEMENT OF THE CASE 2

A. The Basic Structure Of The Medical Device Amendments 2

1. Legislative Background 2

2. Device Classification 3

3. Exceptions To The Premarket Approval Process 4

4. State Regulatory Efforts And Preemption Under the MDA 6

B. Facts 7

C. Proceedings And Decisions Below 8

SUMMARY OF THE ARGUMENT 10

ARGUMENT 14

I. THERE IS NO PREEMPTION OF DAMAGES CLAIMS UNDER THE MDA, AS EVIDENCED BY ITS LANGUAGE, HISTORY, AND PURPOSE 16

A. 21 U.S.C. § 360k(a) Does Not Preempt State-Law Damages Claims 16

B. Other Provisions Of The MDA Confirm That 21 U.S.C. § 360k(a) Does Not Preempt State-Law Damages Claims. 23

C. The Purpose And History Of The MDA Confirm That Damages Claims Are Not Preempted Under Section 360k(a) 28

II. EVEN IF SECTION 360k(a) PREEMPTS SOME DAMAGES CLAIMS, IT DOES NOT DO SO IN THIS CASE 34

A. The 510(k) Notification Process Does Not Impose A Federal Requirement That Preempts The Lohrs' Claims 34

B. No Other Federal Requirements Preempt Any Of The Lohrs' Claims. 39

1. In Order To Have Preemptive Effect Under Section 360k(a), Federal Requirements Must Be Device-Specific And Subject-Specific 39

2. None Of The Lohrs' Claims Is The Subject Of Any Specific Federal Requirement 42

III. THE LOHRS' CLAIMS ARE NOT PREEMPTED TO THE EXTENT THAT THEY RELY ON FEDERAL STANDARDS. 45

CONCLUSION 47

APPENDIX 1a

TABLE OF AUTHORITIES

CASES

Pages

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456 U.S. 63 (1982) 22, 32

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48 F.3d 965 (6th Cir. 1995) 31

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143 F.R.D. 141 (S.D. Ohio 1992),
appeal dismissed,
14 F.3d 600 (6th Cir. 1993),
cert. denied, 115 S. Ct. 294 (1994) 32

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115 S. Ct. 552 (1994) 18

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709 F. Supp. 662 (D. Md. 1989) 24, 31

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467 U.S. 837, 842-45 (1984) 15, 41

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505 U.S. 504 (1992) 12, 17, 19, 20, 30, 41

Commissioner v. Lundy,
116 S. Ct. 647 (1996) 18

Duncan v. Iolab Corp.,
12 F.3d 194 (1994) 9

English v. General Electric Co.,
496 U.S. 72 (1990) 15

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115 S. Ct. 1483 (1995) 23, 38, 41, 42

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501 U.S. 452 (1991) 15

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642 N.E.2d 206, 204 Ill. Dec. 744
(Ill. App. 1994) 18, 22, 29

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114 S. Ct. 2239 (1994) 15, 16

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69 F.2d 809 (2d Cir. 1934),
aff'd, 293 U.S. 465 (1935) 33

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471 U.S. 707 (1985) 11, 13, 15, 25, 32, 42, 46

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1990 U.S. Dist. Lexis 17409
(S.D.N.Y. Dec. 21, 1990) 32

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367 U.S. 303, 307 (1961) 18

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430 U.S. 519 (1977) 15

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835 F. Supp. 1015 (E.D. Mich. 1993),
appeal pending, No. 94-1502 (6th Cir.) 32

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67 F.3d 1453 (9th Cir. 1995) 18, 20, 26, 42

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983 F.2d 1130 (1st Cir.),
cert. denied, 114 S. Ct. 84 (1993) 32

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680 F. Supp. 1293 (D. Minn. 1989) 24

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837 P.2d 1273 (Haw. 1992) 35

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18 F.3d 13 (1st Cir. 1994) 32

Moore v. Kimberly-Clark Corp.,
867 F.2d 243 (5th Cir. 1989) 14, 31, 43

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850 F. Supp. 633 (S.D. Ohio 1994) 21, 27, 28

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A.H. Robins Co.,
545 F. Supp. 1177 (D. Mass. 1982) 21

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Dispensers v. Long,
75 N.J. 544, 384 A.2d 795 (1978) 24, 31

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115 S. Ct. 1671 (1995) 23

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appeal pending, No. 95-1085 (10th Cir.) 42

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cert. denied, 114 S. Ct. 300 (1993) 10

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113 S. Ct. 2187 (1993) 12, 27

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331 U.S. 218 (1947) 15

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369 U.S. 1 (1962) 22

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464 U.S. 238 (1984) 15, 28, 29, 30

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961 F.2d 1330 (7th Cir.), *cert. denied*,
113 S. Ct. 327 (1992) 26, 32

Smith v. Pingree,
651 F.2d 1021 (5th Cir. Unit B 1981) 20, 31

Smith v. United States,
113 S. Ct. 2050 (1993) 18

Sullivan v. Stroop,
496 U.S. 478 (1990) 11, 18

Tetuan v. A.H. Robins, Co.,
738 P.2d 1210 (Kan. 1987) 31

United States Department of Treasury v. Fabe,
113 S. Ct. 2202 (1993) 19

Wisconsin Public Intervenor v. Mortier,
501 U.S. 597 (1991) 15, 46

STATUTES AND BILLS

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21 U.S.C. § 351(f)(2)(B) 5

21 U.S.C. § 360(k) 5, 13, 34

21 U.S.C. § 360c(a)(1)(A) 3

21 U.S.C. § 360c(a)(1)(B) 3, 4

21 U.S.C. § 360c(a)(1)(C) 4

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21 U.S.C. § 360c(f)(1)(A) 5

21 U.S.C. § 360c(f)(3) 35

21 U.S.C. § 360e(b) 5, 7

21 U.S.C. § 360e(b)(1)(A) 4

21 U.S.C. § 360e(b)(1)(B) 5

21 U.S.C. § 360e(c)(1) 4

21 U.S.C. § 360e(d)(2) 4

21 U.S.C. § 360h(d) 12, 27, 28

21 U.S.C. § 360i(a) 3

21 U.S.C. § 360j(e) 41

21 U.S.C. § 360j(f) 3

21 U.S.C. § 360j(g) 41

21 U.S.C. § 360k 31

21 U.S.C. § 360k(a) . . . . . *passim*

21 U.S.C. § 360k(b) 7, 12, 23, 24, 25, 27

21 U.S.C. § 360j(i)(1) 34

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REGULATIONS

21 C.F.R. § 10.85(e) 21

21 C.F.R. § 801.109(c) 43

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21 C.F.R. § 807.97 . . . . . 13, 36

21 C.F.R. § 807.100 34

21 C.F.R. § 807.100(a)(4) 34

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21 C.F.R. § 807.100(b)(1) 34

21 C.F.R. § 807.100(b)(2) 35

21 C.F.R. § 808.1(b) 26

21 C.F.R. § 808.1(d) 10, 13, 21, 40, 45

21 C.F.R. § 808.1(d)(1) 23

21 C.F.R. § 808.1(d)(2) 14, 45

21 C.F.R. § 808.1(d)(3) 23, 40, 41

21 C.F.R. § 808.1(d)(6) 23

21 C.F.R. § 808.1(d)(6)(i) 46

21 C.F.R. § 808.1(d)(6)(ii) 14, 25, 41, 43

21 C.F.R. § 808.1(d)(8) 23

21 C.F.R. § 808.5(b)(2) 24

21 C.F.R. § 808.20(a) 12, 25

21 C.F.R. § 808.20(c)(1) 12, 25, 26

21 C.F.R. § 808.20(d) 26

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21 C.F.R. § 814.1(c)(1) 4

21 C.F.R. § 814.20 4

21 C.F.R. § 814.45(c) 6

21 C.F.R. Part 820 . . . . . 14, 44

21 C.F.R. § 820.80 45

21 C.F.R. § 820.81 45

21 C.F.R. § 820.130 44

21 C.F.R. §§ 820.160-.62 46

21 C.F.R. § 820.56(b) 44

21 C.F.R. § 820.56(d) 44

21 C.F.R. § 860.3(c)(3) 4

21 C.F.R. § 870.3680(b) 7, 38

21 C.F.R. § 870.3680(c) 7, 38

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2d Sess. (1976) 2, 3, 6, 12, 22, 29, 30, 37

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On Writ of Certiorari to the United States
Court of Appeals for the Eleventh Circuit

BRIEF FOR CROSS-PETITIONERS
LORA LOHR AND MICHAEL LOHR

OPINIONS BELOW

The opinion of the court of appeals is reported at 56 F.3d 1335 (11th Cir. 1995), and is reproduced in the appendix to the petition in No. 95-754 ("Pet. App.") at 1a. The unreported opinion of the United States District Court for the Middle District of Florida is reproduced at Pet. App. 1b.

JURISDICTION

The judgment of the court of appeals was entered on July 3, 1995. Cross-respondent filed a timely petition for rehearing and suggestion for rehearing in banc on July 24, 1995, which the court of appeals denied on August 15, 1995 (Pet. App. 1e). The petition for writ of certiorari in No. 95-754 was filed on November 13, 1995, and the cross-petition was filed on December 6, 1995. The Court granted the petition and the cross-petition on January 19, 1996. This Court has jurisdiction under 28 U.S.C. § 1254(1) and Rule 12.5 of this Court.

STATUTES AND REGULATIONS INVOLVED

The principal statutes and regulations involved in this case are reproduced in the appendix to this Brief ("App.").

STATEMENT OF THE CASE

Approximately five years ago, a pacemaker manufactured by cross-respondent Medtronic, Inc., and implanted in cross-petitioner Lora Lohr, failed suddenly, causing injuries to Ms. Lohr and requiring her to undergo emergency surgery. Pet. App. 6a. The question presented is whether cross-petitioners are entitled to seek compensation for their injuries under Florida common law, or whether, as Medtronic maintains, a federal law enacted in 1976, for the purpose of protecting consumers from potentially dangerous medical devices, was intended to bar their access to their state tort systems entirely.

A. The Basic Structure Of The Medical Device Amendments.

1. Legislative Background.

Under federal law, a "medical device" includes a vast array of products, such as tongue depressors, band-aids, tampons, bone screws, hip replacements, artificial heart valves, and pacemakers. *See* 21 U.S.C. § 321(h). Prior to 1976, medical devices were largely unregulated. Although the Food and Drug Administration ("FDA") had limited authority to seize adulterated and misbranded devices already on the market, it lacked the authority to prevent the entry of a medical device on the market that it had had for many years with respect to drugs. *See* H.R. Rep. 853, 94th Cong., 2d Sess. 8-10 (1976)("*House Report*"); *see id.* at 11 (a "serious drawback of the existing authority is that FDA cannot act against a hazardous medical device until after it is on the market").

By the mid-1970's, the peril of this regulatory gap had become clear. There had been a series of public health hazards caused by dangerous devices. Most notable was the defectively designed Dalkon Shield intrauterine device, which had entered the market without regulatory scrutiny and had caused numerous deaths and thousands of serious injuries to otherwise healthy women. *See House Report*, at 8; S. Rep. 33, 94th Cong., 1st Sess. 1-2, 6-7, *reprinted in* 1976 U.S.C.C.A.N. 1070-72, 1075-76.

In 1976, responding to the preventable harms caused by such devices, *id.*, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act. Pub. L. No. 94-295, 90 Stat. 539 (1976)(codified at 21 U.S.C. § 360c *et seq.*). The principal purpose of the MDA was to increase consumer protection by preventing the distribution of dangerous devices and providing a structure through which devices would reach the market. *See House Report*, at 1-12. Congress placed authority for implementing the MDA in the Secretary of Health, Education, and Welfare (now Health and Human Services), who delegated that responsibility to the FDA. *Id.* at 13.

2. Device Classification.

Under the MDA, each medical device falls into one of three classes, depending on its medical importance and its potential for causing harm to patients. *House Report*, at 34. Class I devices, such as tongue depressors, are those for which the MDA's "general controls" applicable to all devices, such as recordkeeping and good manufacturing guidelines, *see* 21 U.S.C. §§ 360i(a), 360j(f), are sufficient to provide reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(A).

Class II devices, such as tampons, 21 C.F.R. § 874.3300(b)(2), are those for which general controls alone are insufficient to protect public health. *See* 21 U.S.C. § 360c(a)(1)(B). Although the statute originally required the FDA

to promulgate performance standards for Class II devices, not a single standard was ever issued. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 523 & n.82 (1988); S. Rep. 513, 101st Cong., 2d Sess. 15 (1990). Thus, in 1990, Congress amended the MDA to make Class II devices subject to "special controls," which may include, in the FDA's discretion, performance standards, post-market surveillance, patient registries, and other measures deemed appropriate by the FDA. Pub. L. No. 101-629, § 5(a), 104 Stat. 4517-18 (1990); *see* 21 U.S.C. § 360c(a)(1)(B).

Finally, Class III devices are those which operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients. 21 U.S.C. § 360c(a)(1)(C); *see* 21 C.F.R. § 860.3(c)(3). In theory, Class III devices must undergo premarket approval ("PMA") by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA. *See* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The manufacturer's PMA application must also contain proposed labeling for the device, a sample of the device, and other information. *See generally id.* The FDA may grant premarket approval only if it finds that there is "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e(d)(2).

3. Exceptions To The Premarket Approval Process.

The PMA process does not apply to the vast majority of devices because of two related exceptions. First, a device on the market prior to the effective date of the 1976 Act—a so-called "grandfathered" device—was not required to undergo premarket approval, even if it was a Class III type of device. *See, e.g.*, 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Manufacturers

of pre-MDA devices do not have to seek premarket approval until 30 months have passed since the FDA classified the device in Class III, *and* 90 days have elapsed since the FDA's issuance of a final regulation calling for PMA applications for that specific type of device. 21 U.S.C. §§ 360e(b), 351(f)(2)(B).

Second, a device marketed *after* the MDA's effective date—such as the pacemaker implanted in Lora Lohr (*see* Pet. App. 6a)—may bypass the PMA process if the device is "substantially equivalent" to either a "grandfathered" pre-MDA device, or a Class I or Class II device. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A). This exception to premarket approval, known as the "510(k)" process, simply requires the manufacturer to notify the FDA under section 510(k) of the Act of its intent to market the device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA "predicate device." 21 U.S.C. § 360(k); *see id.* § 360c(f)(1). The 510(k) process is much less expensive than obtaining a PMA and has other marketing advantages as well. *See* Pet. App. 19a n.14 (*citing* Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J.L. & Tech. 1, 47 & n.273 (1989)).[1]

Section 510(k) notifications are required for most Class I and Class II devices, but premarket approval is not a part of the statutory design for those devices. With respect to Class III devices, however, substantial equivalence was intended as a stop-gap measure, so that companies that sold grandfathered devices did

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[1] *See also* Adler, *supra*, 43 Food Drug Cosm. L.J. at 516 ("A 510(k) notification requires little information, rarely elicits a negative response from FDA, and gets processed very quickly"); Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510, 515-18 (1984)(describing the substantial marketing advantages of section 510(k) over PMA in terms of having to provide far less information to FDA, significantly higher FDA allowance rates, and speed of disposition).

not gain a competitive advantage during the period in which the FDA classified devices and implemented the statute, after which both pre- and post-MDA Class III devices would be required to undergo PMA. Kahan, *supra*, 39 Food Drug Cosm. L.J. at 514-15; Adler, *supra*, 43 Food Drug Cosm. L.J. at 513; *see House Report*, at 30; S. Rep. 513, *supra*, at 14-15. In fact, the FDA has not yet required PMAs for most Class III devices, and over 80 percent of them—including critical devices, such as pacemakers—enter the market *without* premarket approval (*i.e.*, as substantial equivalents to grandfathered devices). H.R. Rep. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307. Significantly, unlike the PMA process, the 510(k) notification process does not call for scrutiny of a device's safety and effectiveness. *Compare* 21 C.F.R. § 814.45(c)(PMA), *with id.* § 807.100(b)(510k).

4. State Regulatory Efforts And Preemption Under the MDA.

During the MDA enactment process, Congress was informed of state regulatory programs, most notably in California, that had stepped into the federal regulatory vacuum and required that devices undergo premarket approval before their commercial distribution. *House Report*, at 45 (noting that California required PMA for intrauterine devices). Concluding that state premarket scrutiny, even if not uniform, was preferable to no premarket scrutiny at all, Congress crafted a provision that would permit state regulatory programs to remain in place until the FDA had implemented specific counterpart federal regulations, but thereafter would preempt conflicting state and local regulatory measures. *Id.* Thus, 21 U.S.C. § 360k(a) provides that States may not "establish or continue in effect with respect to a device ... any requirement" that is "different from, or in addition to" certain federal device "requirements" issued under the MDA. 21 U.S.C. § 360k(a)(reproduced in App. 1a). Even then, Congress authorized

the FDA to grant state and local governments exemptions from preemption for their medical device laws in certain circumstances. *See* 21 U.S.C. § 360k(b)(discussed *infra* at 23-27).

B. Facts.

This case involves injuries caused by a Medtronic pacemaker and its related components, including the lead, which is a wire connected to the pacemaker that delivers the electrical impulse to the heart. *See* Pet. App. 6a; 21 C.F.R. § 870.3680(b)(describing "permanent pacemaker electrode"). Although pacemaker leads were classified as Class III devices more than 16 years ago, 45 Fed. Reg. 7943, 7945 (Feb. 5, 1980), the FDA has never issued a regulation under 21 U.S.C. § 360e(b) calling for PMA applications for such devices. *See* 21 C.F.R. § 870.3680(c)("No effective date has been established of the requirement for premarket approval" for pacemaker leads). The particular lead in question is Medtronic's Model 4011. R1-37, Ex. 1, ¶ 6.[2]

On October 20, 1982, Medtronic notified the FDA of its intent to market the Model 4011. R1-37, Ex. 1, at Ex. A.[3] In a letter issued 40 days later, the FDA stated that the device had been found substantially equivalent to a pre-MDA device. *Id.* The FDA told Medtronic that it could market the device subject only to the Class I "general controls" applicable to all devices. *Id.*

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[2] Record citations in the form "R1-37" refer to the district court record. The first figure refers to the volume number of the record, the second refers to a particular document by docket number, and the third reference, if any (*e.g.*, Ex. 1), refers to a specific portion of that document.

[3] Letter from Robert G. Britain, Associate Director for Device Evaluation, Office of Medical Devices, National Center for Devices and Radiological Health, Food and Drug Administration, to Edward W. Numainville, Product Regulation Manager, Medtronic, Inc. (Nov. 30, 1982)(reproduced in App. 10a).

The FDA emphasized that "this letter does not in any way denote official FDA approval of your device," and warned the company about creating any "misleading" impression to the contrary. *Id.* Thus, the Model 4011 lead reached the market solely on the basis of its substantial equivalence to devices that themselves were never evaluated for safety and effectiveness. As a government report specifically analyzing the repeated failures of Medtronic's pacemaker leads explained:

> As of 1984, 15 new Medtronic polyurethane-insulated pacemaker leads had been marketed since the first was introduced in 1977. Because each new lead was determined to be "substantially equivalent" to a previously marketed lead ... each one "piggybacked" on its predecessors through FDA's 510(k) review process. This process does not require FDA to determine that any of these models are safe and effective — and FDA has not done so.

U.S. General Accounting Office, *Medical Technology: For Some Cardiac Pacemaker Leads, the Public Health Risks are Still High* 1 (GAO/PEMD-92-20 Sept. 1992).

In January 1987, cross-petitioner Lora Lohr was implanted with a Medtronic pacemaker, including the 4011 lead. On December 30, 1990, Ms. Lohr's pacemaker failed, resulting in a "complete heart block," which required her to undergo emergency surgery and replacement of her pacemaker. Complaint ¶¶ 4, 7, Eleventh Circuit Record Excerpts ("RE") 7, 8. Her treating physician attributed the pacemaker failure to a defect in the lead. Pet. App. 6a; *see* Dep. of Robert L. Pekaar, M.D., at 13, 26-28 (Sept. 8, 1993), R1-28 (exhibit folder).

C. Proceedings And Decisions Below.

Cross-petitioners Lora and Michael Lohr filed this case on March 9, 1993, in Florida state court. The complaint alleged that Medtronic had designed, manufactured, and assembled its

pacemaker in an unreasonably dangerous manner and that the pacemaker was prone to sudden, catastrophic failure. The complaint further alleged that Medtronic had failed to warn Ms. Lohr or her physicians of the product's tendency to life-threatening failure, despite Medtronic's knowledge of other prior failures. As a result of the pacemaker's failure, Ms. Lohr suffered pain, scarring, physical handicap, and mental suffering, and sought compensation for those injuries, as well as for future expenses to be incurred in restoring her health. Michael Lohr, Lora Lohr's husband, claimed loss of consortium based on his wife's injuries. Complaint, ¶¶ 8, 9-14, RE 8-9.

Medtronic removed the case to the United States District Court for the Middle District of Florida under 28 U.S.C. § 1441 on the basis of diversity of citizenship. Pet. App. 6a. It then filed a motion for summary judgment on the ground that the Lohrs' tort claims were preempted by 21 U.S.C. § 360k(a), the MDA provision which concerns state-law "requirements" that are "different from, or in addition to" certain federal requirements established under the MDA. Pet. App. 7a. The district court denied the motion, holding that the Lohrs' common-law claims would not pose an obstacle to the objectives of the MDA. Pet. App. 5d. The court subsequently reversed itself and granted summary judgment to Medtronic in light of the Eleventh Circuit's decision in *Duncan v. Iolab Corp.*, 12 F.3d 194 (1994)(per curiam), which the district court interpreted as requiring preemption of all product liability claims concerning a medical device. Pet. App. 2b.

The Eleventh Circuit reversed in part and affirmed in part. It began by noting that, under its *per curiam* decision in *Duncan*, section 360k(a) preempted at least *some* common-law tort claims. Pet. App. 11a. The court of appeals also ruled that the section 510(k) process, because it merely "grandfathers" onto the market devices that are similar to pre-MDA devices, does not itself establish preemptive "requirements." Pet. App. 27a ("the 510(k)

process is focused on equivalence, not safety"). The court further held that there were no MDA requirements relating to device design applicable to the pacemaker leads that could be said to preempt the Lohrs' design-defect claim under section 360k(a). Pet. App. 26-29a.

However, the Eleventh Circuit also held that the Lohrs' failure-to-warn and manufacturing-defect claims were preempted, not on the basis of specific MDA requirements relating to warnings for, or the manufacture of, pacemaker leads, but on the basis of the FDA's regulations pertaining to prescription device labeling and good manufacturing, which are applicable to medical devices generally. Pet. App. 29a-32a. To reach that result, the court relied on an FDA regulation which, as a prerequisite to preemption of a state device requirement under section 360k(a), demands that there be a "specific counterpart [FDA] regulation[]" or "other specific requirement[] applicable to a particular device under the act...." 21 C.F.R. § 808.1(d). In doing so, the court rejected the Lohrs' claim that, under section 808.1(d), the federal requirement must be specific to the particular type of device—here, pacemaker leads—in order to trigger preemption under section 360k(a). Pet. App. 20a-21a.

Finally, despite the language of section 360k(a), which preempts only those state and local requirements that are "different from, or in addition to" requirements under the MDA, the court of appeals held that the Lohrs' manufacturing-defect and failure-to-warn claims would be preempted even if they sought only to enforce the federal MDA requirements in those areas. The court found one of its prior preemption rulings controlling on that issue. *See* Pet. App. 13a (*citing Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir.), *cert. denied*, 114 S. Ct. 300 (1993)).

SUMMARY OF THE ARGUMENT

Medtronic's position is that 21 U.S.C. § 360k(a) grants device manufacturers a blanket tort immunity. This view is at

odds with the MDA's text, structure, history, and purpose, and with authoritative FDA regulations concerning the scope of MDA preemption. Nowhere in the MDA or its legislative history did Congress so much as hint, let alone express in "clear and manifest" terms, *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985), that the Act comprehensively abolished state common-law remedies historically available to injured medical device users. Against the backdrop of a series of public health tragedies in which patients died or were seriously injured by defective medical devices, Congress enacted the MDA "to assure the[ir] safety and effectiveness." Conference Report, H.R. Rep. 1090, 94th Cong. 2d Sess. 1 (1976). It is unthinkable that Congress would have left injured medical device consumers with no means of obtaining compensation for their injuries, and with significantly *less* protection than they had prior to the MDA's enactment.

I. Under 21 U.S.C. § 360k(a), a State may not "establish or continue in effect with respect to a medical device" a "requirement" that is "different from, or in addition to" certain "requirements" "applicable to" a medical device under the MDA. The term "requirement" in section 360k(a) encompasses only positive law, such as statutes and regulations, rather than damages actions, and thus does not reach the Lohrs' claims for compensation under Florida common law.

Section 360k(a) refers once to state-law "requirements" that are candidates for preemption and twice to federal "requirements" that may have preemptive effect. The federal "requirements" flow solely from positive law—the MDA and its regulations. To interpret state-law "requirements" as including actions for damages would thus run counter to the basic rule of statutory construction that multiple uses of the same word in the same statute should be accorded the same meaning. *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990). The MDA's legislative history confirms this view, as it refers to the statute's state-law requirements as "regulations," a

term which does not include common law, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 519 (1992), and mentions only positive enactments of state legislatures as candidates for preemption. H.R. Rep. 853, 94th Cong., 2d Sess. 45-46 (1976).

Further, section 360k(a) preempts only state-law requirements "with respect to a device." Unlike state statutory or regulatory requirements which tell device manufacturers how to produce their devices, the general common-law duties under which the Lohrs seek compensation are not requirements "with respect to a device" under section 360k(a). Rather, if the Lohrs prevail at trial, Medtronic will be obligated only to pay damages, but it will not be *required* to do anything with "respect to [the] device."

Two other MDA provisions further demonstrate that the common law is beyond the reach of section 360k(a). First, 21 U.S.C. § 360k(b) permits the FDA to grant states exemptions from preemption for any state "requirement" that is preempted under section 360k(a). Subsection (b), however, does not apply to damages claims, as shown both by its text and the FDA's implementing regulations. For example, the FDA's regulations—which are entitled to deference—contemplate exemptions only for "any statute, rule, regulation or ordinance" that a state has "enacted." 21 C.F.R. §§ 808.20(a), 808.20(c)(1). Thus, the presence of subsection (b) in the statute bolsters the conclusion that section 360k(a) does not apply to damages actions. *See Rake v. Wade*, 113 S. Ct. 2187, 2193 (1993).

Second, 21 U.S.C. § 360h(d) provides that, even where the FDA orders a manufacturer to repair or replace a faulty medical device, compliance with the order "shall not relieve" the manufacturer "from liability under ... State law." This provision shows that Congress understood that the MDA and state tort law would coexist, and that it did not intend the enactment of landmark consumer protection legislation to immunize medical device manufacturers from product liability actions.

II. Quite apart from whether 21 U.S.C. § 360k(a) can, under some circumstances, preempt common-law claims, the claims in this case are not preempted because there are no preemptive federal requirements "applicable to" the pacemaker lead implanted in Lora Lohr. Under section 360k(a), state law concerning medical devices may be preempted only if there are device-specific federal requirements, either in the MDA itself or in regulations issued by the FDA, that directly conflict with the requirements established under state law. *See also* 21 C.F.R. § 808.1(d).

Medtronic's pacemaker lead entered the market through the MDA's 510(k) notification procedures, under which Medtronic marketed the device based on its substantial equivalence to a device that was grandfathered onto the market when the MDA was enacted in 1976. *See* 21 U.S.C. § 360(k); 21 C.F.R. § 807.87. That process did not establish any requirements pertaining to the device's safety and effectiveness—much less any such requirements that conflict with the Lohrs' common-law claims. *See id.* § 807.97. Moreover, because there are no specific manufacturing or labeling requirements applicable to the device, there is no preemption of the Lohrs' damages claims, which are premised on defective manufacture of the device and Medtronic's failure to warn of its prior problems.

This understanding of 21 U.S.C. § 360k(a) is confirmed by the FDA's preemption regulations, which are entitled to substantial deference. *Hillsborough County*, 471 U.S. at 713. They provide that preemption may occur only

> when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act....

21 C.F.R. § 808.1(d). Under this regulation, for there to be preemption, there must be federal requirements specific to

pacemaker leads that address the same subject matters upon which the Lohrs' state-law suit is based.

The court of appeals held that the Lohrs' manufacturing-defect and failure-to-warn claims were preempted by the FDA's good manufacturing and prescription labeling guidelines, which apply to devices *generally*. Those holdings are at odds with the regulatory command that the federal requirement be applicable to a "particular device." *Accord* 21 C.F.R. § 808.1(d)(6)(ii); *see also Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989)(federal regulation requiring a specific warning for tampons preempted common-law duty-to-warn claim, but not claims that device was defectively designed and manufactured, in absence of specific federal design or manufacturing requirements for tampons). Because pacemaker leads are not subject to any device-specific manufacturing or labeling specifications, they are not subject to any requirements that preempt the Lohrs' common-law claims based on manufacturing defects or a duty to warn.

III. Finally, even if the Lohrs' claims were held to be "requirements" that could trigger preemption under section 360k(a), those claims could still go forward if the state-law duties on which the suit is based did not contravene federal standards in those areas. This conclusion is required by the plain terms of section 360k(a), which preempt state requirements only if they are "different from, or in addition to" federal law, not if they apply the same substantive standards. *See also* 21 C.F.R. § 808.1(d)(2). Here, for instance, the Lohrs' manufacturing-defect claim could proceed based on the standards set out in the FDA's general manufacturing guidelines. *See* 21 C.F.R. Part 820.

ARGUMENT

Several important aspects of this Court's jurisprudence converge in this case. First, despite the supremacy of federal law whenever applicable, a party seeking preemption of state law bears a heavy burden. There is a strong presumption against preemption

that may be overcome only by "clear and manifest" congressional intent to the contrary. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985); *see also Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991).

This presumption is even stronger where, as in this case, preemption would displace the historic power of the states to protect the health and safety of their citizens. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Moreover, where preemption of common-law claims would leave injured individuals without any state *or* federal remedy, which is the result sought by Medtronic here, this Court ascribes preemptive intent to Congress only in the most compelling circumstances. *English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). These basic precepts are not mere precedential idiosyncracies, but are deeply embedded in the "federal-state balance" fundamental to the constitutional plan. *Hillsborough County*, 471 U.S. at 717; *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Thus, the "plain statement rule" of the Court's Supremacy Clause jurisprudence "is nothing more than an acknowledgement that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991).

Finally, in the preemption context, as in others, the views of an agency charged with administering a statutory scheme are entitled to substantial deference. *Hillsborough County*, 471 U.S. at 714-15 (*citing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984)). Here, the MDA is accompanied by a considerable body of FDA regulations and other authoritative agency pronouncements which narrowly construe the MDA's preemptive effect and establish that the Lohrs' claims are not preempted.

I. THERE IS NO PREEMPTION OF DAMAGES CLAIMS UNDER THE MDA, AS EVIDENCED BY ITS LANGUAGE, HISTORY, AND PURPOSE.

With due regard for the foregoing principles, the ultimate touchstone of preemption analysis is congressional intent. *Hawaiian Airlines*, 114 S. Ct. at 2243. Thus, the question presented here is whether, in enacting the MDA, Congress intended to eliminate state-law damages claims of the sort brought by the Lohrs. In this regard, it is important to understand the breadth of Medtronic's position in this case. Medtronic argues not only that 21 U.S.C. § 360k(a) reaches some damages claims, but that marketing a device on the basis of substantial equivalence to a pre-MDA device preempts all common-law claims, including those based on negligence in device design and manufacture and on failure to warn of known hazards from use of the product. In effect, Medtronic argues that, in enacting a consumer protection statute, the 94th Congress simultaneously barred access to the tort system for patients injured by potentially life-threatening medical devices.

Congress, however, did not enact such a radical incursion into the common law of the 50 states. Taken together, the language of the MDA's preemption provision, 21 U.S.C. § 360k(a), other relevant provisions of the MDA, the statute's history and purpose, and the FDA's preemption regulations, demonstrate that the express preemption provision of section 360k(a) does not foreclose any state-law damages suits seeking compensation for injuries caused by medical devices.

A. 21 U.S.C. § 360k(a) Does Not Preempt State-Law Damages Claims.

Analysis of congressional intent begins with the language of the MDA's preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a)(App. 1a). Although the word "requirement" was construed in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), to encompass common-law claims in the specific context of one of the preemption provisions at issue there, "requirement" as used in section 360k(a) was intended to preempt only positive state law, not common-law tort claims, because the context here is very different from that in *Cipollone*.

1. *Cipollone* interpreted the term "requirement" only in the context of the Public Health Cigarette Smoking Act of 1969 ("the 1969 Act"). Because it did not hold that "requirement" *must* include the common-law whenever it is used, *Cipollone* did not resolve the question whether the word "requirement" as used in the MDA covers damages actions. Indeed, as *Cipollone* noted in holding that there was no preemption of common-law claims under the Federal Cigarette Labeling and Advertising Act of 1965 (the 1969 Act's predecessor), "[t]here is no general, inherent conflict between [express] federal pre-emption of state [regulatory] requirements and the continued vitality of state common law damages actions." 505 U.S. at 518. Thus, *Cipollone* recognized that Congress can, and often does, expressly preempt only state positive law.

"Language, of course, cannot be interpreted apart from context." *Smith v. United States*, 113 S. Ct. 2050, 2054 (1993); *see also Brown v. Gardner*, 115 S. Ct. 552, 555 (1994)("a word is known by the company it keeps")(*citing Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961)). In section 360k(a), "requirement" appears three times. The latter two uses of the term are references to federal requirements and, therefore, must refer to requirements imposed pursuant to statute or regulation under the MDA. These two uses do not refer to damages remedies or to the common law, because they are not the kinds of "requirements" applicable to devices under federal law. *See Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1460-61 (9th Cir. 1995)(Reinhardt, J., concurring); *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 209-10, 204 Ill. Dec. 744 (Ill. App. 1994); Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 926 (1995).

The first use of "requirement" in section 360k(a), on which Medtronic relies, refers to the actions of states and their political subdivisions that are candidates for preemption under the MDA. The term is not modified in any way to distinguish it from the latter two uses, nor does it contain any embellishment or reference to damages actions or to the common law. Thus, the first use of "requirement" can include common-law damages actions only if it means something different from the subsequent uses of that term in the very same sentence.

However, there "is no reason to believe that Congress meant the term [requirement] to mean one thing" in the first part of section 360k(a) "but to mean something else altogether" the next two times it appears. *Comm'r v. Lundy*, 116 S. Ct. 647, 655 (1996). To the contrary, "the interrelationship and close proximity of these provisions ... 'present a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.'" *Id.* (*quoting Sullivan v. Stroop*, 496 U.S. 478, 484

(1990)(internal quotations and case citations omitted)); *see also, e.g., United States Department of Treasury v. Fabe*, 113 S. Ct. 2202, 2215 (1993) (Scalia, J., dissenting) (referring to foregoing principle as "basic rule of statutory construction").

These multiple uses of the word "requirement" in section 360k(a) sharply differentiate this case from *Cipollone*. There, "requirement" was used only once: "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 505 U.S. at 515 (quoting relevant statutory language). The use of "requirement" thus referred to the totality of "State law," which reasonably may include common law and which was critical to the *Cipollone* plurality's holding that some common-law claims were within the statute's preemptive reach. *Id.* at 522-23. Further, the 1969 Act made no mention at all of *federal* "requirements." Instead, it used *different* nomenclature—"labeled in conformity with the provisions of this Act"—to refer to the means by which the 1969 Act has preemptive effect. *Id.* at 515. Here, by contrast, the language of section 360k(a) does not target for preemption the totality of "State law," and, as explained above, this very provision uses "requirement" twice to refer only to federal positive law.

2. Under section 360k(a), only state requirements "with respect to a device" are candidates for preemption. This language also demonstrates that preemption under section 360k(a) is limited to state positive law. The duties under which tort plaintiffs seek compensation are not duties "with respect to a device," but rather are general obligations concerning the conduct of persons who manufacture and sell all types of products. For instance, the Lohrs seek compensation under common-law duties that obligate all manufacturers to design and manufacture their products with due care and to warn of their products' dangers. Even if those duties

were "requirements" in some sense, they are not requirements "with respect to a device" under section 360k(a).

On the other hand, the positive-law requirements to which section 360k(a) is directed are, in fact, requirements "with respect to a device." For example, a Florida statute requires that specific labeling appear on hearing-aid packages before the hearing aid may be sold. *See Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981). That requirement "with respect to a device" properly raised a preemption question because of its potential conflict with the FDA's hearing-aid labeling regulations. *See* 21 C.F.R. § 801.420; *see also* 21 C.F.R. §§ 808.53-.101 (governing status of similar positive state-law requirements under section 360k(a)).

This contrast between positive-law requirements "with respect to a device" and general common-law duties underscores a fundamental difference between the purposes of the two regimes. Like the Florida statute, a "requirement with respect to a device" obligates the seller to take a particular action concerning the device, for instance, to label the device in a particular manner or to manufacture it to certain specifications. If the seller does not satisfy the requirement, it cannot sell the device. Like the Lohrs' claims here, however, common-law claims do not require manufacturers to take any action with respect to a device. Thus, if the Lohrs prevail at trial, Medtronic will be obligated only to compensate the Lohrs. At some point, tort verdicts in cases involving Medtronic's 4011 lead may prompt the company to take some action with "respect to [the] device," but those verdicts will not *require* Medtronic to do so. This distinction drawn by section 360k(a) between positive law and common law reflects what, as noted earlier, the plurality recognized in *Cipollone*: "There is no general, inherent conflict between [express] federal pre-emption of state [regulatory] requirements and the continued vitality of state common law damages actions." 505 U.S. at 518. *See Kennedy*, 67 F.3d at 1459.

The FDA has interpreted section 360k(a) in the same manner. In promulgating its preemption regulations, the agency stated that many state statutes "are not requirements 'with respect to a device' within the meaning of [section 360k(a)] because they generally pertain either to persons who manufacture devices or distribute devices...,and not directly to devices. In order for a State provision to be a requirement with respect to a device within the meaning of [section 360k(a)]—and thereby a candidate for preemption—it must relate to the device itself." 43 Fed. Reg. 18661, 18663 (May 2, 1978). *Cf.* 21 C.F.R. § 808.1(d)(no preemption under section 360k(a) of requirements of general applicability that apply to other products in addition to devices, such as uniform commercial code and unfair trade practices statutes); *see also Mulligan v. Pfizer*, 850 F. Supp. 633, 636 (S.D. Ohio 1994)(rejecting preemption of generally applicable common-law rules, contrasted with specific Ohio statute with respect to hearing aids).[4]

Because common-law duties such as those relied on by the Lohrs are not requirements with respect to a device, they are not preempted under section 360k(a).

3. Finally, section 360k(a) states that "[n]o State or political subdivision of a State may establish or continue in effect" certain

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[4] Accordingly, in a 1984 advisory opinion, the FDA rejected the preemption holding in *National Women's Health Network, Inc. v. A.H. Robins Co.*, 545 F. Supp. 1177 (D. Mass. 1982), where the plaintiff sought a warning to Dalkon Shield users under Massachusetts common law. The advisory opinion—which is binding on the agency, *see* 21 C.F.R. § 10.85(e)—stated that "the act preempts only State and local requirements that directly and specifically relate to devices." Letter From Joseph P. Hile, Associate Commissioner for Regulatory Affairs, FDA, to National Women's Health Network (Mar. 8, 1984), App. 12a-13a. As the advisory opinion concluded, "[r]ules or requirements established by States to govern the legal remedies available under the State judicial system are not 'requirements with respect to a device' within the meaning of [21 U.S.C. § 360k(a)]."

device "requirements." Construing an award of damages to a tort plaintiff as "establishing or continuing in effect" a device requirement is at odds with this Court's oft-stated "assum[ption] 'that the legislative purpose is expressed by the ordinary meaning of the words used.'" *American Tobacco Co. v. Patterson*, 456 U.S. 63, 68 (1982)(*quoting Richards v. United States*, 369 U.S. 1, 9 (1962)); *see Haudrich*, 642 N.E.2d at 210. That "ordinary meaning" is confirmed in two respects.

First, in 1976, when the MDA was enacted, Congress was aware that states might "establish" programs to regulate medical devices, since some states had already done so. *House Report*, at 45. Thus, it is reasonable to assume that section 360k(a)'s reference to the "establishment" of device "requirements" meant the enactment of state medical device programs. At the same time, the duties relied on by tort claimants are general duties under the common law that had been "established" over hundreds of years. Thus, section 360k(a)'s limited prohibition on the future "establishment" of device requirements simply could not have been a reference to common-law duties.

Second, while a post-1976 jury award in a device case would represent confirmation of a pre-existing common-law duty—for instance, the duty to act non-negligently—only an inept grammarian would describe an award of damages in a tort case as "continuing in effect [a requirement] with respect to a device." On the other hand, it is common parlance to say that a previously-"established" statute or regulation remains in force or "continues in effect."[5]

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[5] The FDA's preemption regulations, discussed in greater detail *infra* at 25-27, describe in considerable detail whether, and in what circumstances, specific types of state and local statutes, regulations, and ordinances are preempted under section 360k(a). Those regulations do not mention damages remedies, providing further confirmation that the MDA was not intended to affect such remedies. *See* 21 C.F.R. §§

(continued...)

* * *

In sum, the rule that intent to preempt be "clear and manifest" and the related presumption against preemption applies not only to the existence of preemption, but also to its scope. *E.g., New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995). Here, the language of section 360k(a) taken as a whole falls far short of the requisite plain statement and demonstrates that common-law claims are not preempted.[6]

B. Other Provisions Of The MDA Confirm That 21 U.S.C. § 360k(a) Does Not Preempt State-Law Damages Claims.

1. The existence of subsection (b) of 21 U.S.C. § 360k further manifests Congress' understanding that subsection (a) does not preempt damages claims. Subsection (b) permits states to seek exemptions from the FDA for their device laws that would otherwise be preempted under subsection (a). The language of subsection (b) parallels that of subsection (a) and allows a "State or political subdivision" to exclude from preemption state "requirements" that are "applicable to a device for human use."

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[5](...continued)
808.1(d)(1)(state electrical codes, uniform commercial codes, and state unfair trade practice statutes), 808.1(d)(3)(state and local licensing and certification provisions), 808.1(d)(6)(state and local device enforcement provisions, and misbranding and adulteration statutes), 808.1(d)(8)(state and local provisions for raising revenue or fees); *see also* App. 14a (Letter from Chief of FDA's Regulatory Staff stating that, in the FDA's view, product liability law is not preempted by section 360k(a)).

[6] While section 360k(a) does not preempt any damages claims, we acknowledge the possibility that a state tort action against a medical device manufacturer could be preempted in certain limited circumstances based on conflict preemption principles. *See Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1487-88 (1995).

See App. 1a-2a. In other words, subsection (b) allows the FDA to grant exemptions for any type of requirement that may be preempted under subsection (a).

Although subsections (a) and (b) apply to the same "requirements," the statutory language, the FDA's preemption regulations, and common sense make clear that subsection (b) does not include judgments in tort actions. First, it is difficult to imagine the basis for a state to obtain an exemption for a damages action in light of the relevant statutory criteria: that the state requirement be (1) more stringent than the federal requirement, or (2) required by "compelling local conditions." 21 U.S.C. § 360k(b). Without considering the evidence advanced by particular tort plaintiffs or reviewing jury instructions in hundreds of cases, it would be infeasible, if not impossible, for a state to seek a blanket exemption for its common law on the ground that it was "more stringent" than federal law. Furthermore, it makes little sense to say that providing compensation to medical device victims is "compell[ed] by local conditions," rather than by a state's general interest in assuring that its citizens have remedies for their injuries.

Nor could Congress have expected states to petition the FDA for exemptions for individual plaintiffs on a case-by-case basis. As one court put it, "if the term 'requirement' were interpreted so as to include tort law, the exemption provision [of § 360k(b)] would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of an IUD tort plaintiff?" *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989); *accord Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1298 (D. Minn. 1989) (*dicta*); *cf. New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 384 A.2d 795, 813-14 (1978)(existence of § 360k(b) is strong evidence of narrow preemptive scope of § 360k(a)). *See also* 21 C.F.R. § 808.5(b)(2)(indicating that state requirements are not eligible for exemption from preemption unless they have been "issued in final

form," which, when applied to tort claims, would be after final judgment).

In short, the state-law "requirements" referred to in sections 360k(a) and 360k(b) are co-extensive, and plainly state-law "requirements" under subsection (b) cannot rationally be construed to include damages claims. Thus, interpreting section 360k(a) "requirements" to include damage claims would be at odds with the canon of statutory construction that repeated uses of the same word in the same statute—here, in the very next subsection—should be accorded the same meaning. *See supra* at 17-19.

The FDA is of the same view. The agency's regulations implementing section 360k(b)—which are entitled to deference, *Hillsborough County*, 471 U.S. at 714-15—begin by stating that a "State or political subdivision may apply . . . for an exemption from any requirement it has *enacted* and that is preempted...." 21 C.F.R. § 808.20(a)(emphasis added)(App. 7a-9a). Similarly, the FDA requires state and local governments to submit "any *statute, rule, regulation or ordinance*" with respect to each "requirement" for which an exemption is sought. *Id.* (emphasis added)(App. 5a). All applications seeking exemption from preemption must identify the "title of the chief administrative officers of the State or local agency that has primary responsibility for administration of the requirement," 21 C.F.R. § 808.20(c)(1), which would be nonsensical with respect to damages claims since they are not "administered" by state or local "agenc[ies]." *See also* 21 C.F.R. § 808.1(d)(6)(ii)(in deciding whether state requirement is preempted in first instance, "the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the *statute*...")(emphasis added). Thus, the FDA has construed "requirement" under both subsections (a) and (b) identically and

in neither context has it included jury awards or common-law claims.[7]

The FDA has also encouraged state and local governments to obtain the agency's views on the MDA's preemptive scope before enacting new device laws. As the FDA put it, an "advisory opinion might be sought or issued when a State or local government is contemplating the issuance of a *statute or regulation*. In such cases, the advisory opinion could address the question of whether the *rule or regulation* as proposed would be preempted under section" 360k(a). 42 Fed. Reg. at 30385 (emphasis added); *see also id.* (making references to state requirements as "statutes," "regulations," "ordinances," and "relevant background material including legislative histories, hearing reports, and similar material"). In addition, the FDA has indicated that a state "requirement" is not "eligible for exemption from preemption" unless it has been "issued in final form." 21 C.F.R. § 808.5(b)(2) (App. 7a). Only regulations and ordinances and similar enactments, not common-law duties, are "issued in

[7] Several courts have incorrectly assumed that state tort law can be preempted because of an FDA regulation stating that a "court decision" may be subject to preemption under section 360k(a). 21 C.F.R. § 808.1(b); *see, e.g., Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1331 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992). However, the term "court decision," read in context, refers to judicial decrees enforcing or interpreting state positive law. *See Kennedy*, 67 F.3d at 1461-62 (Reinhardt, J., concurring). In commentary issued when it proposed 21 C.F.R. § 808.1(b), the FDA stated that, in considering requests for exemption, it "must know whether the statute, rule, or regulation has been subject to judicial or administrative interpretations that give it legal meanings in the State or political subdivision that are not readily apparent from the face of the document"). 42 Fed. Reg. 30383, 30385 (June 14, 1977); *accord* 43 Fed. Reg. 18661, 18663 (May 2, 1978). Thus, in requesting that states submit any relevant "statute, rule, regulation, or ordinance," the FDA's regulations explain that "[i]f the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall" submit copies of such interpretations. 21 C.F.R. § 808.20(c)(1); *see also id.* § 808.20(d).

final form." Thus, the FDA's regulations regarding section 360k(b) provide further confirmation that the term "requirement" as used throughout section 360k was not intended to cover damages claims. *See Rake v. Wade*, 113 S. Ct. 2187, 2193 (1993)("statutory terms are often clarified by the remainder of the statutory scheme--because the same terminology is used elsewhere in a context that makes [its] meaning clear").[8]

2. Subsection (d) of 21 U.S.C. § 360h also confirms the Lohrs' understanding of section 360k(a). Under section 360h, the FDA has the power to notify health professionals and the public of unreasonable risks associated with devices and to order device manufacturers to repair, replace, or provide refunds with respect to devices that pose such risks. "Of vast significance" to the preemption analysis, *Mulligan*, 850 F. Supp. at 636, is subsection (d), entitled "Effect on Other Liability." That subsection provides:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

[8] This reading of section 360k(b) is further substantiated by the fact that, although the states have sought exemptions from preemption in a series of regulatory proceedings before the FDA, 45 Fed. Reg. 67321-67338 (Oct. 10, 1980); *see* 21 C.F.R. §§ 808.53-.101, to our knowledge, *no* state has *ever* sought an exemption for jury awards or common-law duties. Indeed, many states have indicated their belief that common-law duties are not preempted by section 360k(a). *See* Brief of Alabama *et al.* in Support of Petition for Writ of Certiorari in *King v. Collagen Corp.*, No. 92-1979 (U.S. filed Aug. 18, 1993) (*amicus* brief signed by 28 state attorneys general urging review by this Court on ground that MDA preemption does not reach common-law claims); Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 927.

Thus, section 360h(d) "specifically contemplates state law liability and damages" against manufacturers of medical devices, even after the FDA issues an order under section 360h. *Mulligan*, 850 F. Supp. at 636. Considered in conjunction with the statute's other provisions, the FDA's regulations, and the presumption against preemption, section 360h(d) is powerful evidence that the statute contemplated that state-law damages actions would coexist with MDA regulation. *Id.* As the Court observed in *Silkwood* in a related context, "the only congressional discussion concerning the relationship between the ... [statute] and state tort remedies indicates that Congress assumed that such remedies would be available." 464 U.S. at 251.

C. The Purpose And History Of The MDA Confirm That Damages Claims Are Not Preempted Under Section 360k(a).

The MDA's purpose and history also demonstrate that section 360k(a) preempts only positive state-law enactments. The MDA was passed "to protect the public health by amending the Federal Food, Drug, & Cosmetic Act to assure the safety and effectiveness of medical devices." Conference Report, H.R. Rep. 1090, 94th Cong. 2d Sess. 1 (1976). The Senate Report directly traced the Act's origins to the Dalkon Shield disaster:

> On January 28, 1975, the Health Subcommittee conducted a hearing which once again underlined the urgency of enacting medical device legislation. The hearing focused on the Dalkon shield, an IUD which was used by two million American women, and hundreds of thousands of women overseas, before the very significant health hazards of the device became known. All witnesses before the Committee, including the Commissioner of the Food and Drug Administration, testified that many of the deaths and much of the illness attributed to this device could have been prevented if medical device legislation, as provided in the reported bill, had been in effect when the Dalkon shield was developed.

S. Rep. 33, 94th Cong., 1st Sess. 1-2, *reprinted in* 1976 U.S.C.C.A.N. 1070-72. As the bill's sponsor stated on the Senate floor, the focus of the MDA is on consumer protection: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975) (Sen. Kennedy).

Prior to enactment of the MDA, individuals could and did seek redress for injuries caused by medical devices through state-law damages actions. *House Report*, at 8. Congress' concern with the injuries caused by the Dalkon Shield surely did not impel it to *decrease* the remedies available to injured device users. In fact, Congress was aware of the important function played by the many suits brought against the Dalkon Shield's manufacturer. The House Committee that sponsored the legislation cited these suits as evidence of the enormity of the public health tragedy that could have been avoided had effective federal regulation been in place. *House Report*, at 8; *see also* S. Rep. 33, 94th Cong., 1st Sess. 1-2, *reprinted in* 1976 U.S.C.C.A.N. 1070-71. Having acknowledged the role of the civil justice system both in bringing the Dalkon Shield problem to light and in compensating the victims, Congress surely would not, in the same breath, have "remove[d] all means of judicial recourse" for the victims of such future calamities without a word to that effect. *See Silkwood*, 464 U.S. at 251.[9]

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[9] This point was well put by the Illinois Court of Appeals in *Haudrich v. Howmedica, Inc.*, 642 N.E.2d at 211 (citations omitted):

> [T]he primary purpose of the 1976 Medical Device Amendments was "to assure the reasonable safety and

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Moreover, while the legislative history mentions nothing about preemption of damages claims, it *does* say something about the types of state law that *are* preempted. The House Report states that once a particular MDA requirement was in place, that requirement would preempt corresponding statutory provisions "governing *regulation* of devices by States and localities." House Report, at 45. The Report specifically mentions the 1970 California medical device statute. *Id.* The committee's reference to the California statute and similar enactments as state *regulation* is significant because *Cipollone* emphasized repeatedly that "the term 'regulation' most naturally refers to positive enactments, not to common-law remedies." 505 U.S. at 519; *see also id.* at 523 (same).

The legislative history's silence on preemption of damages remedies and its concomitant discussion of the potential for preemption of state regulatory programs take on even greater significance in light of this Court's precedents, which not only establish a presumption against preemption, but also require unmistakable evidence of preemptive intent to abolish common-law remedies where federal law provides no damages remedy. *See, e.g., Silkwood*, 464 U.S. at 251. Here, the MDA contains no express private right of action for damages, and courts are in agreement that there is no implied right of action under the Food,

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[9](...continued)
effectiveness of medical devices intended for human use." If safety was Congress' primary purpose, it would be strange for Congress to eliminate the safety aspects inherent in tort litigation by destroying tort litigation in the entire country with the same statute it passed to promote safety. It would be stranger still for Congress to take such dramatic action without even mentioning it as a consequence of the passage of a bill that was debated for years. Yet the debate and Congressional record are barren of any indication that Congress intended to preempt court decisions by passing the 1976 Medical Device Amendments.

Drug, and Cosmetic Act, of which the MDA is a part. *See Bailey v. Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995)(reviewing case law). It would be inimical to this Court's Supremacy Clause jurisprudence to hold, as Medtronic urges, that Congress deprived consumers of *any* means of obtaining compensation for their injuries, where the statute makes no mention of preemption of common-law claims and where nothing in the legislative history so much as hints at such a drastic result.[10]

Finally, in stark contrast to recent lower court rulings that section 360k(a) preempts an array of common-law claims, no court came to such a conclusion for 15 years after the MDA's enactment. In the MDA's early years, the states obtained the FDA's views on whether their medical device statutes and regulations were preempted, *see, e.g.*, 45 Fed. Reg. 67321-67338, while the tort system continued unaffected. *E.g., Tetuan v. A.H. Robins, Co.*, 738 P.2d 1210 (Kan. 1987). Case law construing 21 U.S.C. § 360k concerned the MDA's preemptive effect on positive law, with most courts holding that even those regulatory efforts were not preempted in the absence of specific federal regulations on the same subject as the state regulation. *See, e.g., Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981); *New Jersey Guild*, 384 A.2d 795.

As late as 1989, the only serious question regarding preemption of damages actions was whether, in light of a specific FDA-mandated warning label for tampon packaging, tort claimants harmed by defective tampons could maintain suit on the ground that the warning was inadequate. *Compare, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), *with Callan*, 709 F. Supp. 662. Not until 1992 did any appellate court rule that

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[10] *See also* Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 924 & n.130 ("Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages because 'a common law right of action [already] exists'")(quoting legislative history).

preemption occurred merely because the defendant marketed a device through FDA procedures, *e.g.*, *Slater*, 961 F.2d 1330; *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), or that the MDA's general controls—which are applicable to all devices—had preemptive effect on garden-variety negligence and strict liability claims. *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18 (1st Cir. 1994).[11]

While this history did not, of course, inform the 94th Congress that enacted the MDA, it is nonetheless significant to the question now before the Court. Since statutes are to be interpreted according to their "ordinary meaning," *American Tobacco Co.*, 456 U.S. at 68, and preemption exists only where that is Congress' "clear and manifest" intent, *Hillsborough County*, 471 U.S. at 715, then surely if section 360k(a)'s purpose was comprehensive "tort reform," that purpose would not have taken so long to emerge. To the contrary, for 15 years the MDA was recognized

[11] One example of the post-1976 vitality of the tort system for those injured by medical devices is the tragedy involving the Shiley convexo-concave heart valve, a device given premarket approval by the FDA in 1979. Hundreds of Shiley heart valve patients have died because manufacturing and design defects make the valve prone to fracture. *See generally The Bjork-Shiley Heart Valve: "Earn As You Learn,"* Staff Report of the Subcommittee on Oversight and Investigations of the Energy and Commerce Committee of the U.S. House of Representatives, 101st Cong., 2d Sess., Comm. Print 101-R (Feb. 1990). Despite the valve's PMA, "hundreds of lawsuits" were brought during the 1980's, which were not dismissed on preemption grounds, leading to very substantial settlements. *In re Pfizer Securities Litig.*, 1990 U.S. Dist. Lexis 17409, *5 (S.D.N.Y. Dec. 21, 1990). Indeed, as late as 1992, Pfizer, Inc., Shiley's parent, entered into a class action settlement which, among other things, guaranteed $500,000 to $2,000,000 to fracture victims and their survivors. *Bowling v. Pfizer*, 143 F.R.D. 141, 150 (S.D. Ohio 1992), *appeal dismissed*, 14 F.3d 600 (6th Cir. 1993), *cert. denied*, 115 S. Ct. 294 (1994). It was not until 1993 that a reported decision appeared preempting any of the many lawsuits involving the Shiley valve. *Kemp v. Pfizer*, 835 F. Supp. 1015, 1020-21 (E.D. Mich. 1993), *appeal pending*, No. 94-1502 (6th Cir.).

for precisely what it was—much-needed consumer protection legislation, with a modest preemption provision enacted to override positive state law in particular circumstances.[12]

* * *

Statutory interpretation requires more than an arid focus on one word or phrase in isolation. As Learned Hand put it more than 60 years ago, "the meaning of a sentence may be more than that of the separate words, as a melody is more than the notes, and no degree of particularity can ever obviate recourse to the setting in which all appear, and which all collectively create." *Helvering v. Gregory*, 69 F.2d 809, 810-11 (2d Cir. 1934), *aff'd*, 293 U.S. 465 (1935). In keeping with that view, the task here demands that the words of section 360k(a) be interpreted together and in the context of the statute as a whole, and with deference to the views of the agency charged with its administration. Seen from that perspective, section 360k(a) does not include damages claims, and

[12] The current Congress also apparently believes that the MDA does not preempt common-law claims. The House of Representatives passed a bill in 1995 that, among other things, would eliminate punitive, but not compensatory, damages recoverable against medical device manufacturers in cases where the device received FDA approval. *See* H.R. 956, 104th Cong., 1st Sess. § 201(f)(1995)(reprinted and debated in 141 Cong. Rec. H2941-H2948)(Mar. 9, 1995)); 141 Cong. Rec. H3027 (Mar. 10, 1995)(passed). Similar legislation has been considered several times before, beginning as early as 1977. *See* Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 940-42 & nn.185-189; *see also, e.g.*, S. 687, 103d Cong., 1st Sess. § 203(b)(2)(A)(1993). These provisions would not merely be superfluous if the MDA had already eliminated common-law claims, but would substantially *increase* the remedies available to tort victims in bills that were intended to have precisely the opposite effect. The 1995 bill also provides a limit of $250,000 on noneconomic damages, such as those for pain and suffering and emotional distress, in "any health care liability action," defined to include actions against medical device manufacturers. H.R. 956, § 203. That provision also would be superfluous if Congress had eliminated tort liability against medical device manufacturers in 1976.

the Eleventh Circuit's decision upholding Medtronic's preemption defense should be reversed.

II. EVEN IF SECTION 360k(a) PREEMPTS SOME DAMAGES CLAIMS, IT DOES NOT DO SO IN THIS CASE.

A. The 510(k) Notification Process Does Not Impose A Federal Requirement That Preempts The Lohrs' Claims.

The court of appeals correctly rejected Medtronic's argument that the 510(k) notification procedure establishes a preemptive safety and effectiveness "requirement applicable ... to" the Model 4011. Pet. App. 27a. As noted earlier, in October 1982, Medtronic notified the FDA that its Model 4011 pacemaker lead was substantially equivalent to a pre-MDA device, which gave Medtronic the right to market the product 90 days thereafter. App. 10a; *see* 21 U.S.C. § 360(k)(1982).[13]

At that time, "substantial equivalence" was not defined by statute, and the FDA required only that the manufacturer's 510(k) notification include basic information directed toward showing the device's similarity to a predicate device. 21 C.F.R. § 807.87 (1982). In 1990, Congress defined "substantial equivalence." Pub. L. No. 101-629, § 12, 104 Stat. 4523 (1990)(codified at 21 U.S.C. § 360j(i)(1)); *see also* 57 Fed. Reg. 58403 (1992)(codified at 21 C.F.R. § 807.100). Under that definition, a manufacturer need only show that the device has the same intended uses and technological characteristics as the predicate device, regardless of the predicate device's safety and effectiveness. 21 C.F.R. § 807.100(b)(1). And even if the device does *not* share the same

[13] Since 1992, the FDA has forbidden the marketing of 510(k) products until it has determined that the device is substantially equivalent. 57 Fed. Reg. 58403 (Dec. 10, 1992)(codified at 21 C.F.R. § 807.100(a)(4)). In 1982, not even this was required.

technological characteristics as the predicate device, it may *still* be deemed substantially equivalent, if the manufacturer can show that the device is equivalent in safety and effectiveness to the predicate device (which itself was not reviewed for safety and effectiveness). *Id.* § 807.100(b)(2).[14]

Therefore, at the time the Model 4011 was marketed, Medtronic's only obligation was to submit a notification explaining the basis for its claim of substantial equivalence to a pre-MDA device. That action alone allowed Medtronic to market the device 90 days later. But even assuming that the 1990 statutory definition had been applied to the Model 4011 when it entered the market in 1982, and assuming further that the lead did *not* share the same technological characteristics as its predecessors (which cannot be determined from the record), the device entered the market simply because the FDA believed that the device was neither less safe nor less effective than a "grandfathered" device, which itself had never been reviewed for safety and effectiveness. Thus, even under these extremely generous assumptions, the 4011 lead was marketed and implanted in Lora Lohr without any agency review (much less approval) for safety and effectiveness, and without the imposition of any "requirements" specific to the pacemaker's manufacture or labeling. *See Larsen v. Pacesetters Systems, Inc.*, 837 P.2d 1273, 1281-82 (Haw. 1992).

For this reason, the FDA's letter issued in response to Medtronic's 510(k) notification made no mention of the device's safety or effectiveness nor of its manufacturing processes or its

[14] In 1990, Congress required manufacturers submitting Class III 510(k) notifications to submit summaries of, and citations to, all adverse safety and effectiveness data concerning the predicate device. Pub. L. No. 101-629, § 4(a), 104 Stat. 4515 (1990)(codified at 21 U.S.C. § 360c(f)(3)). This obligation does not impose any "requirements" on the design, manufacturing, or labeling of 510(k) products and does not, in any event, apply to Medtronic's October 1982 510(k) notification for the Model 4011 lead.

design, and it did not approve the device's labeling—the areas of potential overlap with the common-law duties invoked in the Lohrs' complaint. App. 10a; *see* Complaint, ¶ 6, R.E. 8. The FDA added that its letter "does not in any way denote official FDA approval of your device" and warned Medtronic about creating any "misleading" impression to the contrary. App. 11a. These admonitions, which track 21 C.F.R. § 807.97 (App. 2a), are fully consistent with an independent government study of the failures of Medtronic's pacemaker leads, including the Model 4011, which explained that the "substantial equivalence [process] ... does not require FDA to determine that any of these models are safe and effective—and FDA has not done so." *See* U.S. General Accounting Office, *Medical Technology: For Some Cardiac Pacemaker Leads, the Public Health Risks are Still High* 1 (GAO/PEMD-92-20 Sept. 1992).[15]

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[15] Many other governmental reports and commentators have made the same point. *See, e.g.*, House Comm. on Energy and Commerce, *Less Than the Sum of its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administrations's Center for Devices and Radiological Health*, 103d Cong., 1st Sess., Committee Print 103-N, Report No. ISBN 0-16-040891-1, at 8-9 (May 1993)("Officials at the [FDA's] Center for Devices and Radiological Health point out that a finding of substantial equivalence does not represent, and should not be construed as, a statement of a device's safety and effectiveness. It means only that the device is substantially equivalent to a preamendment Class I, II, or III device [footnote omitted])"; Adler, *supra*, 43 Food Drug Cosm. L.J. at 516 ("[S]ubstantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective"); Kahan, *supra*, 39 Food Drug Cosm. L.J. at 515-16 (1984)(same, but explaining that some 510(k) reviews are more extensive than others); U.S. Dept. of Health and Human Services, Office of Inspector Gen'l, *Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Review Process*, ID No. A-15-89-00065, at 10-11 (continued...)

Significantly, in a regulatory pronouncement that is dispositive here, the FDA has announced that states are free to impose requirements for Class III 510(k) devices that, like the Model 4011 pacemaker lead, are not subject to a federal PMA regulation. Because some states required PMAs for certain devices, *see House Report*, at 45, during the FDA's promulgation of its preemption regulations, commenters asked whether state PMAs would be preempted even before the FDA had required a federal PMA for the particular device in question, *i.e.*, when the device was marketed solely under section 510(k). 43 Fed. Reg. at 18,664 (final rule). The FDA determined that users of Class III devices in states with PMA requirements should not have less protection from unsafe products while the MDA was being implemented than they had before the MDA's enactment. Thus, in the interim, a state could require its own PMA for Class III 510(k) devices:

> For a device classified in class III under section 513(d) of the act, the counterpart FDA requirement is established on the date the device can not lawfully be marketed without approval of an application for premarket approval under ... 21 U.S.C. 351(f)(1)(A). Once these FDA requirements are established, different or additional State requirements are preempted.

Id.[16]

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[15](...continued)
(July 5, 1990)(510(k) process does not require submission of device specimen, verification of test results, or premarketing manufacturing inspections, noting that "the 510(k) review process is not intended for determining premarket *approval*")(emphasis in original).

[16] Subsequently, the FDA ruled that California's requirement that certain Class III devices undergo PMA would not be preempted until the FDA required a PMA for the particular device in question. 45 Fed. Reg. (continued...)

As the FDA explained in its November 1982 substantial equivalence letter, Medtronic's Class III pacemaker leads "will be required to undergo premarket approval *at some time in the future.*" App. 10a. But that date has not arrived. 21 C.F.R. § 870.3680(b), (c). Thus, even today, any state may require that pacemaker leads undergo PMA regulation, including ultimate marketing approval (*or disapproval*). Put another way, because state-based PMAs are not preempted for Class III devices subject only to 510(k) regulation (such as Medtronic's pacemaker leads), the states may decide which of those devices may be sold in their states. *See Myrick*, 115 S. Ct. at 1487 (1995)(no preemption of state claim because no federal standard in place). In light of this fact, it is difficult to conceive how the Lohrs' claims can be preempted: Those claims seek only compensation for injuries and stop far short of demanding the type of state-law PMA procedures specifically permitted by the FDA, which tell the manufacturer whether it can market its product at all.

In summary, the 510(k) process does not result in "requirements" within the meaning of 21 U.S.C. § 360k(a). Therefore, claims premised on state-law duties properly to manufacture and to warn about a product are not preempted by the 510(k) process, even assuming that some common-law tort claims are within the ambit of section 360k(a).

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[16](...continued)
at 67323. Responding to comments which suggested that California PMAs should be preempted if the FDA had *proposed* that a Class III device be downclassified, the agency "disagree[d] with the comments' suggestion that the Federal law should preempt premarket approval for a [class III] device recommended for classification into class I or class II. The counterpart FDA requirement for such a device is not established until the date of final classification...." *Id.; accord* 43 Fed. Reg. at 18,664 (state-law performance standard for Class II device preempted only after FDA has established performance standard for that particular device).

B. No Other Federal Requirements Preempt Any Of The Lohrs' Claims.

1. In Order To Have Preemptive Effect Under Section 360k(a), Federal Requirements Must Be Device-Specific And Subject-Specific.

Section 360k(a) provides that there is no preemption unless there is a federal requirement specifically "applicable to the device," and the corresponding state law is "different from, or in addition to" that federal requirement. Thus, even assuming that section 360k(a) reaches damages actions, the Lohrs' claims are preempted by section 360k(a) only if there are federal requirements imposed specifically upon manufacturers of pacemaker leads, and only if those requirements apply to the features of those leads on which the Lohrs' claims are based.

Despite its holding that the section 510(k) notification process does not, in itself, have any preemptive effect, the court of appeals concluded that the Lohrs' duty-to-warn and manufacturing-defect claims were preempted by FDA labeling and good manufacturing guidelines that apply generally to medical devices. However, the proper preemption analysis—as reflected in the FDA's preemption regulations—demands a much closer fit between a federal "requirement" and the relevant state-law duty.

In defining what types of state and local requirements are subject to preemption, the FDA has stated that:

> State or local requirements are preempted *only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act*, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(emphasis added)(App. 3a-4a). When it promulgated these regulations, FDA explained its interpretation of section 360k(a). Looking first to the words chosen by Congress—dictating that there be a pre-existing federal requirement "applicable *to the device*"—the agency found that device-specific federal rules must first be in place before any preemption can occur. 43 Fed. Reg. at 18662 (highlighting italicized statutory language). The FDA further explained:

> Thus, from a plain reading of section [360k] of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. ... [A] prime example is the preemption of divergent State or local requirements relating to hearing aid labeling ..., which occurred when the new FDA hearing aid regulations took effect... . [O]nly requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution.

Id.[17]

This insistence upon device-specific requirements for the same subject matter regulated by the state—which the FDA refers to as the need for "specific counterpart" requirements—is found throughout the FDA's regulations. For instance, the MDA does not preempt state registration or certification schemes for medical professionals simply because they "administer, dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). If, however, the FDA

[17] *See also* 42 Fed. Reg. at 30385 (June 14, 1977)(proposed rule)("a preempting FDA requirement will become applicable to a device within the meaning of section [360k(a)] only after FDA takes a regulatory or administrative action involving the application of a particular requirement of the act to a particular device").

exercises its authority under the MDA to restrict the use of certain devices to particular health professionals, *see* 21 U.S.C. §§ 360j(e),(g), then the federal requirements control, but only to the extent that state and local regulations actually conflict with them. 21 C.F.R. § 808.1(d)(3). And of particular relevance to the Lohrs' duty-to-warn claim, states and localities may prohibit the manufacture of mislabeled devices unless the FDA has established a "specific labelling requirement for a specific device" which conflicts with the state or local requirement. *Id.* § 808.1(d)(6)(ii); *see also Cipollone*, 505 at 524-30 (claims based on alleged deficiencies in the specific warning required by Congress preempted, while claims not in specific conflict with the federal warning not preempted).

The FDA's regulation concluding that preemption occurs only when there is a device-specific federal regulation that is a "specific counterpart" to the state-law requirement is a "permissible construction" of section 360k(a) for two reasons. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984). First, the statute directs that there be a federal requirement "applicable" to a device, which easily supports the FDA's demand for specific counterpart federal requirements. As the FDA explained when it promulgated its regulation, "[t]he phrase 'or in addition to, any requirement applicable under this Act to the device' means that an FDA requirement must exist before preemption can occur." 43 Fed. Reg. at 18662; *see Myrick*, 115 S. Ct. at 1487.

Second, the regulatory determination that federal requirements must be specific to a "particular device" is consistent with the statute's insistence that preemptive requirements relate to "*the* device" under section 360k(a), rather than to requirements that apply to devices generally. Thus, the FDA's demand for device-specific, subject-specific "requirements" under section 360k(a) is entitled to deference as the agency's reasonable

construction of the statute, and it is controlling here. *See Hillsborough County*, 471 U.S. at 714-15.

2. None Of The Lohrs' Claims Is The Subject Of Any Specific Federal Requirement.

In order to evaluate whether a particular claim is preempted, it is necessary to determine whether there is a device-specific counterpart federal requirement that is different from the corresponding state-law claim. *See Kennedy*, 67 F.3d at 1457-59; *Oja v. Howmedica, Inc.*, 848 F. Supp. 905, 907 (D. Colo. 1994), *appeal pending*, No. 95-1085 (10th Cir.). Here, because there are no such specific federal requirements, the Lohrs' claims are not preempted. *See Myrick*, 115 S. Ct. at 1487 (no preemption of state-law tort claim based on failure to install anti-lock brakes, because no standard in place specifically concerning anti-lock brakes).

a. *The Duty-To-Warn Claim.* The Lohrs' duty-to-warn claim is based on the theory that Medtronic should have alerted doctors and patients to the previous failures of its pacemaker leads. There are no specific warning requirements applicable to pacemaker leads, in contrast, for instance, to hearing aids and tampons. 21 C.F.R. §§ 801.420, 801.430. Indeed, as explained earlier, device labeling is *never* approved in conjunction with a 510(k) notification (since all that is required is a finding of substantial equivalence to a pre-MDA device). Further, there is no evidence here that the labeling was even submitted by Medtronic to the FDA during the 510(k) notification process. *See generally* Declaration of Charles H. Swanson, R1-37, Ex. 1 (describing 510(k) submission, but not mentioning submission of labeling); *see also* U.S. General Accounting Office, *Medical Devices: FDA's 510(k) Operations Could Be Improved* 62 (GAO/PEMD-88-14 Aug. 1988)(one third of 510(k) applications contain no labeling at all).

As noted earlier, the FDA has specifically addressed the issue of when federal rules have preemptive effect, using the labeling of hearing aids as an example. The FDA stated that a state's labeling requirements for hearing aids would not be preempted *until the FDA's specific hearing-aid labeling requirements took effect*. 43 Fed. Reg. at 18,662; *accord* 21 C.F.R. § 808.1(d)(6)(ii). On the other hand, the general labeling rules are not device-specific; indeed, they do little more than tell manufacturers to list the device's indications, warnings, contraindications, and the like. *See* 21 C.F.R. § 801.109(c)). Therefore, the court of appeals' reliance on these general rules was erroneous. *See* Pet. App. 32a-33a. They have no preemptive effect on a state's labeling requirements applicable to specific aspects of a particular device, much less on common-law claims.

Thus, even if Congress intended some preemption of damages claims, the Lohrs' duty-to-warn claim is not preempted because there are no specific FDA-required warnings with respect to pacemakers or their leads. *See, e.g., Moore v. Kimberly-Clark*, 867 F.2d 243 (federal regulation requiring a specific warning for tampons preempted a common-law duty-to-warn claim, but not claims that the device was defectively designed and manufactured, in absence of specific federal design or manufacturing requirements for tampons).

b. *The Manufacturing-Defect Claim.* The same kind of analysis applies to the Lohrs' manufacturing-defect claim and results in the same finding of no preemption. According to the Eleventh Circuit, the FDA's general good manufacturing practice ("GMP") regulations preempt the manufacturing-defect claim. Pet. App. 30a. But as the FDA has explained, these regulations are "umbrella" guidelines "applicable to all finished device manufacturers [which] should not be so specific as to prescribe for each manufacturer the precise details of what it must do and how it must undertake to manufacture devices. Rather, the GMP regulation ... contain[s] general requirements in specific areas of

concern to all manufacturers...." 43 Fed. Reg. 31508 (July 21, 1978).

Far from being device-specific requirements, the GMPs are little more than common-sense standards for the production of any product. *See generally* 21 C.F.R. Part 820. For instance, the regulation regarding device packaging states that "[t]he device package and any shipping container for a device shall be designed and constructed to protect the device from alteration and damage during the customary conditions of processing, storage, handling, and distribution." 21 C.F.R. § 820.130. Similarly, the FDA's "contamination control" regulation states in its entirety that "[t]here shall be procedures designed to prevent contamination of equipment, components, or finished devices by rodenticides, insecticides, fungicides, fumigants, hazardous substances, and other cleaning and sanitizing substances. Such procedures shall be documented." *Id.* § 820.56(b); *see also, e.g., id.* § 820.56(d)("*Sewage and refuse disposal.* Sewage, trash, by-products, chemical effluents, and other refuse shall be disposed of in a timely, safe, and sanitary manner").

* * *

The ramifications of Medtronic's position warrant some discussion. Approximately 98 percent of all devices—whether Class I, Class II, or Class III—enter the market as substantial equivalents to pre-MDA devices. H.R. Rep. 808, *supra*, at 14, *reprinted in* 1990 U.S.C.C.A.N. 6307. As the FDA informed Medtronic with respect to the Model 4011, these devices are subject only to the MDA's general controls. App. 10a. Thus, if Medtronic's expansive view of the preemptive effect of section 510(k) and the Act's general controls were accepted, the MDA would virtually eradicate state tort law as applied to medical devices. For instance, if the MDA's general manufacturing guidelines have preemptive effect, a patient bacterially infected by a Class I band-aid, *see* 21 C.F.R. § 880.5240, would be barred from obtaining state-law compensation. Similarly, under

Medtronic's view of the statute, if a fetal heart monitor, *id.* § 884.2600, failed to alert a physician to fetal distress because one of its components had been damaged as a result of the manufacturer's improper storage, an action for damages against the manufacturer would be preempted by the FDA manufacturing guidelines, even though they do nothing more than describe prudent manufacturing procedures applicable to any product. *E.g., id.* §§ 820.80, .81 (control of components).

However, these general federal regulatory controls on medical devices, upon which the court of appeals relied, do not establish "requirements" applicable to a "particular device" within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). To hold otherwise, would, under the guise of federal preemption, legislate a comprehensive abolition of state product liability law for medical devices that Congress did not debate and did not intend.

III. THE LOHRS' CLAIMS ARE NOT PREEMPTED TO THE EXTENT THAT THEY RELY ON FEDERAL STANDARDS.

Even if the Lohrs' common-law claims alleging defective manufacture and failure to warn were held to be "requirements" sufficient to trigger preemption under section 360k(a), the Lohrs' claims could still go forward if the state-law duties under which compensation is sought did not contravene federal standards in those areas. The court of appeals held, however, that allowing a jury to award damages by reference to a federal standard would usurp the FDA's proper role. Pet. App. 13a.

The court of appeals' decision in this regard is flawed for several reasons. First, it is at odds with section 360k(a)'s plain language which—whatever its other limits—does not preempt state requirements unless they are "different from, or in addition to" an applicable federal requirement. *See* 21 C.F.R. § 808.1(d)(2)("substantially identical" state or local requirements not preempted). Thus, claims that seek only to enforce federal

standards should not be preempted under any circumstances. For instance, petitioners' manufacturing-defect claim under Florida common law, like many such claims, will be tried, at least in part, based on the failure of Medtronic to manufacture its device in conformance with its specifications, *see* Complaint, ¶ 6, R.E. 8, and could easily be submitted to the jury in a manner that tracks the highly generalized federal standards on that subject. *See* 21 C.F.R. §§ 820.160-.62. In that case, since the Lohrs' claim would support, not undermine, the relevant federal norm, there would be no reason for preemption to apply.

Second, under the court of appeals' reasoning, the states would retain the ability to enforce federal standards under their regulatory regimes, which would have a direct effect on manufacturer conduct. *See* 21 C.F.R. § 808.1(d)(6)(i); 45 Fed. Reg. at 67322. However, an award of damages based on state incorporation of federal standards would be preempted, even though its principal purpose would be to provide compensation, with the only effect on primary conduct, if any, being incidental and entirely consistent with federal standards. Thus, the court of appeals' reasoning would result in a preemption regime under which enforcement of state positive law would receive *more* protection from the incursions of federal law than would damages claims—a bizarre result since neither the statute nor its legislative history makes any mention of common-law preemption at all.

Finally, the obliteration of common-law remedies that go no further than federal law, like all of Medtronic's arguments, runs headlong into the presumption against preemption. This Court has been loathe to find preemption of state law without a clear statement by Congress, even in cases involving the use of state positive law to impose requirements that are the subject of comprehensive federal health and safety legislation. *Mortier*, 501 U.S. at 609-11; *Hillsborough County*, 471 U.S. at 713-16. In cases such as this, where preemption would mean that the Lohrs and thousands of others harmed by medical devices are without

any recompense for their injuries, the Court has been even more exacting in requiring that preemption appear unmistakably in the statutory text and has left it to Congress to enact the kind of sweeping immunity from liability that Medtronic seeks to obtain here by judicial decree.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be reversed, and the case remanded with instructions that all of the Lohrs' claims may go forward.

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APPENDIX

PRINCIPAL STATUTORY PROVISIONS INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360h(d) provides:

Effect on Other Liability

Compliance with an order [to provide notification, repair, replacement, or reimbursement regarding an unsafe device] issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

PRINCIPAL REGULATORY PROVISIONS INVOLVED

21 C.F.R. § 807.97 provides:

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

21 C.F.R. § 808.1 provides:

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements

applicable to medical devices under section 521 [21 U.S.C. § 360k] of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific

counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal requirements shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statues, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

21 C.F.R. § 808.5(b) provides in part:

(2) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations: . . .

A proposed State or local requirement with respect to a device is not eligible for exemption from preemption because the State or local requirement has not been issued in a final form. In such a case, the advisory opinion may indicate whether the proposed requirement would be preempted and, if it would be preempted, whether the Food and Drug Administration would propose to grant an exemption from preemption.

21 C.F.R. § 808.20 provides:

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. An original and two copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr. Rockville, MD 20857. The outside wrapper of any

application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

(c) For each requirement for which an exemption is sought, the application shall include the following information to the fullest extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences.

(3) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(4) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(i) The requirement is more stringent than a requirement applicable to a device under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing how and why the requirement of the

State or political division is more stringent than requirements under the act.

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or materials showing why compliance with the requirement of the State or political subdivision would not cause a device to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions. The application shall also explain in detail the compelling local conditions that justify the requirement.

(5) The title of the chief administrative or legal officers of that State or local agency that has primary responsibility for administration of the requirement.

(6) When requested by the Food and Drug Administration, any records concerning administration of any requirement which is the subject of an exemption or an application for an exemption from preemption.

(7) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(8) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(d) If litigation regarding applicability of the requirement is pending, the State or political subdivision may so indicate in its application and request expedited action on such application.

OTHER RELEVANT MATERIALS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

November 30, 1982

Mr. Edward W. Numainville
Product Regulation Manager
Medtronic Inc.
3055 Old Highway Eight
P.O. Box 1453
Minneapolis, Minnesota
55440

Ref: K822781/A -
Medtronic Models 4011 &
4511
Dated: October 20, 1982
Received: October 21, 1982
Regulatory Class: III

Dear Mr. Numainville:

We have reviewed your premarket notification submission and have found the device to be substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This product has been placed into the regulatory class shown above by a final regulation published in the *Federal Register*. Class I devices are regulated by the general control provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices are those for which future performance standards will be developed; class III devices are those which will be required to undergo premarket approval at some time in the future.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Section 800. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the *Federal Register*. We suggest you subscribe to this publication so that you can convey your view to FDA if you desire. Also, the *Federal Register* will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you need further assistance on the labeling for your device, please contact the Office of Medical Devices, Division of Compliance (HFK-110), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

s/
Robert G. Britain
Associate Director for
Device Evaluation
Office of Medical Devices
National Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

MAR -8 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included

in a requirement applicable to a device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of Section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to advice only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in *National Women's Health Network, et. al.* v. *A.H. Robins Company, Inc.*, No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injunctive remedies. This advisory opinion does not address the merits of the application of such remedies in any action filed by the network in the State of Massachusetts or any other State.

Sincerely yours,
s/
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

FEB 02 1987

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, WA 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,
s/
Joseph M. Sheehan
Chief, Regulations Staff

Enclosures

FILED
MAR 20 1996
CLERK

Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

---

BRIEF FOR CROSS-RESPONDENT MEDTRONIC, INC.

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims alleging defective manufacturing and labeling of a medical device that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

TABLE OF CONTENTS

QUESTION PRESENTED i
TABLE OF AUTHORITIES v
SUMMARY OF ARGUMENT 6
ARGUMENT 8
I. COMMON LAW CLAIMS ESTABLISH STATE REQUIREMENTS SUBJECT TO PREEMPTION UNDER THE FDCA 9
A. This Court Should Reject Plaintiffs' Re-Argument of Issues Resolved in *Cipollone* 9
B. The Language of the FDCA Preemption Provision Encompasses Common Law Claims 12
1. The Preemption Provision's Use of the Term "Requirement" Three Times Does Not Exclude State Common Law Claims 12
2. The FDCA Does Not Restrict Preemption to State Requirements That Apply Exclusively to Devices 13
C. Other Provisions of the FDCA Support Preemption of Common Law Claims 16
II. THE FDCA PREEMPTS PLAINTIFFS' FAILURE-TO-WARN CLAIMS 18
A. The FDCA Establishes Substantial Requirements for Product Warnings Concerning the Model 4011 21
1. The 510(k) Process Imposes Substantial Requirements Concerning Labeling Warnings 21
2. The Prescription Device Labeling Regulation Imposes Substantial Warning Requirements 22

3. The FDCA and Related Regulations Give the FDA Substantial Authority to Require Additional Warnings After Marketing Begins and Prohibit Distribution of Devices with Inadequate Warnings 24
B. The Federal Warning Requirements Have Preemptive Effect Because They Are "Applicable to the Device" 25
C. Plaintiffs' Failure-to-Warn Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011 27
III. THE FDCA PREEMPTS PLAINTIFFS' DEFECTIVE MANUFACTURING CLAIMS 31
A. The FDCA Establishes Substantial Manufacturing Requirements for the Model 4011 32
1. The GMP Regulations Impose Significant Manufacturing Requirements 32
2. The 510(k) Process Imposes Significant Manufacturing Requirements 34
B. The Federal Manufacturing Requirements Have Preemptive Effect Because They are "Applicable to the Device" 34
C. Plaintiffs' Defective Manufacturing Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011 35
1. The GMP Requirements Preempt Plaintiffs' Defective Manufacturing Claims 35

2. The 510(k) Requirements Preempt Plaintiffs' Defective Manufacturing Claims.....38

IV. EVEN IF BASED ON FEDERAL STANDARDS, PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD IMPOSE REQUIREMENTS THAT ARE "DIFFERENT FROM, OR IN ADDITION TO," APPLICABLE FEDERAL REQUIREMENTS.....38

A. State Requirements Are "In Addition To" Federal Requirements Even When They Embody Identical Standards.....40

B. Plaintiffs' Construction of the Statute is Inconsistent With the Congressional Intent to Establish Uniform Requirements.....44

C. The Obligation To Pay Damages Is A "Requirement".....47

CONCLUSION.....50

TABLE OF AUTHORITIES

CASES Page

American Airlines, Inc. v. *Wolens*, 115 S. Ct. 817 (1995).....15,18

Arkansas Louisiana Gas Co. v. *Hall*, 453 U.S. 571 (1981).....5

Baione v. *Owens-Illinois, Inc.*, 599 So. 2d 1377 (Fla. Dist. Ct. App. 1992).....29

Barnett Bank v. *Nelson*, No. 94-1837 (Mar. 26, 1996).....14,20,31

Bourjaily v. *United States*, 483 U.S. 171 (1987).....2

Brown v. *Gardner*, 115 S. Ct. 552 (1994).....11

Cadillac Fairview of Florida, Inc. v. *Cespedes*, 468 So. 2d 417 (Fla. Dist. Ct. App.), review denied mem., 479 So. 2d 117 (Fla. 1985).....39

Central Bank of Denver, N.A. v. *First Interstate Bank of Denver, N.A.*, 114 S. Ct. 1439 (1994).....11

Chevron, U.S.A., Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).....15

Chicago & Northwestern Transportation Co. v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981).....10

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992).....4,6,9,10,11,12,15

Coastal Petroleum Co. v. *American Cyanamid Co.*, 492 So. 2d 339 (Fla. 1986), cert. denied, 479 U.S. 1065 (1987).....13

CSX Transportation, Inc. v. *Easterwood*, 507 U.S. 658 (1993).....4,6,10,11

TABLE OF AUTHORITIES continued

Page

Duvall v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), petition for cert. pending, No. 95-1010 29,30,35

Eli Lilly & Co. v. *Medtronic, Inc.*, 496 U.S. 661 (1990) 12

English v. *General Electric Co.*, 496 U.S. 72 (1990) 4,30

Feldt v. *Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), petitions for cert. pending, Nos. 95-1037, 95-1214 26,29,30,35

Freightliner Corp. v. *Myrick*, 115 S. Ct. 1483 (1995) 30

Garcia v. *United States*, 469 U.S. 70 (1984) 2

Gile v. *Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994) 43

Gillespie v. *United States Steel Corp.*, 379 U.S. 148 (1964) 5

International Paper Co. v. *Ouellete*, 479 U.S. 481 (1987) 10

Jones v. *Rath Packing Co.*, 430 U.S. 519 (1977) 45

Kennedy v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) 8

Kordel v. *United States*, 335 U.S. 345 (1948) 21

Lynnbrook Farms v. *Smithkline Beecham Corp.*, No. 92-2051 (7th Cir. Mar. 21, 1996) 42

Mayor of Georgetown v. *Alexandria Canal Co.*, 37 U.S. (12 Pet.) 91 (1838) 47

McDermott v. *Wisconsin*, 228 U.S. 115 (1913) 30

TABLE OF AUTHORITIES continued

Page

Mendes v. *Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) 28,29,35

Merrell Dow Pharmaceuticals Inc. v. *Thompson*, 478 U.S. 804 (1986) 43,45

Michael v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995) 35

Moore v. *Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) 25

Morales v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) 11,15,18

Murray v. *Briggs*, 569 So. 2d 476 (Fla. Dist. Ct. App. 1990), review denied mem., 581 So. 2d 165 (Fla. 1991) 39

Patterson v. *McLean Credit Union*, 491 U.S. 164 (1989) 11

Pension Benefit Guaranty Corp. v. *LTV Corp.*, 496 U.S. 633 (1990) 11

Pilot Life Insurance Co. v. *Dedeaux*, 481 U.S. 41 (1987) 5

Prather v. *Upjohn Co.*, 797 F.2d 923 (11th Cir. 1986) 29

Rodriguez v. *United States*, 480 U.S. 522 (1987) (per curiam) 2

San Diego Building Trades Council v. *Garmon*, 359 U.S. 236 (1959) 5,10

Silkwood v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984) 4

TABLE OF AUTHORITIES continued

Page

Stanley Industries, Inc. v. *W.M. Barr & Co.*, 784 F. Supp. 1570 (S.D. Fla. 1992).....29

State v. *First National Bank*, 660 P.2d 406 (Alaska 1982).....47

Texas & Pacific Railway v. *Abilene Cotton Oil Co.*, 204 U.S. 426 (1907).....18

Underwriters at LaConcorde v. *Airtech Services*, 493 So. 2d 428 (Fla. 1986).....39

United Construction Workers v. *Laburnum Construction Corp.*, 347 U.S. 656 (1954).....4,5

United States Department of Treasury v. *Fabe*, 113 S. Ct. 2202 (1993).....41

United States v. *11,307 Boxes*, No. 93-574 (S.D. Fla. filed Mar. 26, 1993).....22

United States v. *789 Cases*, 799 F. Supp. 1275 (D.P.R. 1992).....36

United States v. *An Article of Device*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984).....23

United States v. *Articles of Device*, 426 F. Supp. 366 (W.D. Pa. 1977).....23

United States v. *James*, 478 U.S. 597 (1986).....2

United States v. Park, 421 U.S. 658 (1975).....37

United States v. *Undetermined Quantities of Various Articles*, 800 F. Supp. 499 (S.D. Tex. 1992).....33

Witt v. *Norfe, Inc.*, 725 F.2d 1277 (11th Cir. 1984).....36,37

TABLE OF AUTHORITIES continued

Page

Zanzuri v. *G.D. Searle & Co.*, 748 F. Supp. 1511 (S.D. Fla. 1990).....28

STATUTES

7 U.S.C. 4817.....42
15 U.S.C. 1476(a).....42
15 U.S.C. 2075(a).....42
15 U.S.C. 2617(a)(2)(B).....42
21 U.S.C. 321(k).....21
21 U.S.C. 321(m).....20
21 U.S.C. 331.....40
21 U.S.C. 331(q)(1).....47
21 U.S.C. 332.....40
21 U.S.C. 333.....40
21 U.S.C. 334.....24,40
21 U.S.C. 336.....47
21 U.S.C. 337.....43
21 U.S.C. 343-1(a)(1).....41
21 U.S.C. 352.....25
21 U.S.C. 352(a).....24
21 U.S.C. 352(f)(2).....24
21 U.S.C. 352(j).....24
21 U.S.C. 352(t).....47
21 U.S.C. 360c(d)(2)(A).....35
21 U.S.C. 360f.....24
21 U.S.C. 360h.....17,40,47
21 U.S.C. 360h(a).....24,31
21 U.S.C. 360h(a)(2).....28

TABLE OF AUTHORITIES continued

Page

21 U.S.C. 360h(b) 17
21 U.S.C. 360h(b)(3) 5
21 U.S.C. 360h(d) 7,17,18
21 U.S.C. 360h(e) 24,31
21 U.S.C. 360i 24
21 U.S.C. 360j(a) 25
21 U.S.C. 360j(f) 34
21 U.S.C. 360j(f)(1)(A) 32
21 U.S.C. 360j(f)(1)(B) 32
21 U.S.C. 360j(f)(1)(B)(ii) 32
21 U.S.C. 360j(f)(3) 32
21 U.S.C. 360k(a) ..... *passim*
21 U.S.C. 360k(a)(1) 12,20,25,46
21 U.S.C. 360k(a)(2) 2,12,20
21 U.S.C. 360k(b) 4,16
21 U.S.C. 360k(b)(1) 2
21 U.S.C. 360ss 43
21 U.S.C. 678 42
21 U.S.C. 1052(a) 42
21 U.S.C. 1052(b) 43
46 U.S.C. 4306 41
49 U.S.C. 30103(b) 41
Conn. Gen. Stat. Ann. §§ 52-572m to 52-572q (West 1991) 13
Ind. Code Ann. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996) 13
La. Rev. Stat. Ann. §§ 9:2800.51 to 9:2800.59 (West 1991) 13

TABLE OF AUTHORITIES continued

Page

Me. Rev. Stat. Ann. tit. 14, § 221 (West 1980) 13
Miss. Code Ann. § 11-1-63 (Supp. 1994) 13
Mont. Code Ann. § 27-1-719 (1993) 13
N.C. Gen. Stat. §§ 99B-1 to 99B-11 (Michie 1995) 13
Ohio Rev. Code Ann. §§ 2307.71 to 2307.80 (Baldwin 1996) 13
S.C. Code Ann. §§ 15-73-10 to 15-73-30 (Law. Co-op. 1993) 13

REGULATIONS

21 C.F.R. 10.25 5
21 C.F.R. 10.30 5
21 C.F.R. 15.1(b) 32
21 C.F.R. 801.109 22,23,25,28,29
21 C.F.R. 801.109(a)(2) 23
21 C.F.R. 801.109(b)(1) 23
21 C.F.R. 801.109(c) 23,29
21 C.F.R. 807.81(a)(3) 22
21 C.F.R. 807.81(a)(3)(i) 22,34,38
21 C.F.R. 807.87(e) 21
21 C.F.R. 807.87(k) 21
21 C.F.R. 808.1(d)(1) 14
21 C.F.R. 808.1(d)(2) 39
21 C.F.R. 808.1(d)(6)(i) 48
21 C.F.R. 808.20(c)(1) 45
21 C.F.R. 820.5 33
21 C.F.R. 820.25 33
21 C.F.R. 820.46 33

TABLE OF AUTHORITIES continued

Page

21 C.F.R. 820.56 33
21 C.F.R. 820.60 33
21 C.F.R. 820.61 33
21 C.F.R. 820.80 33
21 C.F.R. 820.81 33
21 C.F.R. 820.100 33
21 C.F.R. 820.101 33
21 C.F.R. 820.115 33
21 C.F.R. 820.116 33
21 C.F.R. 820.120 33
21 C.F.R. 820.121 33
21 C.F.R. 820.130 33
21 C.F.R. 820.160 33
21 C.F.R. 820.161 33
21 C.F.R. 820.162 33
21 C.F.R. 820.180 33
21 C.F.R. 820.181 33
21 C.F.R. 820.182 33
21 C.F.R. 820.184 33
21 C.F.R. 820.185 33
21 C.F.R. 820.195 33
21 C.F.R. 820.198 33
21 C.F.R. 895.25 24,31
21 C.F.R. 895.25(a) 24
21 C.F.R. 895.25(a)(3) 24
21 C.F.R. 895.25(b) 24
21 C.F.R. 895.25(d) 24
28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(9) 45

TABLE OF AUTHORITIES continued

Page

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42 Fed. Reg. 30,383 (June 14, 1977) 48,49
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TABLE OF AUTHORITIES continued

Page

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Robert S. Adler & Richard A. Mann, *Preemption & Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895 (1994) 9

U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved (GAO/PEMD-88-14, Aug. 1988) 21

BRIEF FOR CROSS-RESPONDENT MEDTRONIC, INC.

This case involves the construction of 21 U.S.C. 360k(a), the preemption provision of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Medtronic and plaintiffs have taken two markedly different approaches to that question of statutory interpretation. This Court's choice between those two approaches will go a long way toward deciding this case.

Medtronic's approach focuses carefully on the statutory language and structure, and uses legislative history and policy considerations only to reinforce the statute's text or to help clarify its terms. See Pet. Br. 12-49.[1] In contrast, plaintiffs' approach (and that of most of their amici) is dominated by policy arguments, often phrased in the form that a Congress reacting to incidents involving the Dalkon Shield *could not* have intended particular results (e.g., Cross-Pet. Br. 29); by inferences from the *silence* of legislative history (e.g., *id.* at 30); and by *subsequent* "legislative history" and subsequent congressional *inaction* on proposed legislation (e.g., *id.* at 33 n.12). When plaintiffs and most of their amici do pay attention to the statutory language, they do so only by misreading expansive language as if it contained words of narrow limitation. For example, they read the broad statutory phrase "any requirement applicable under this chapter to the device" as if it meant any *safety-ensuring* requirement, see U.S. Br. 19-20, and conclude that a requirement is *not* "applicable to the device" merely because it also applies to things other than the device, see Cross-Pet. Br. 41-42.

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[1] This brief uses the same abbreviations (such as MDA, FDCA, and 510(k) process) used in Medtronic's opening brief. In addition, in this brief "Pet. Br." refers to Medtronic's opening brief, "Cross-Pet. Br." refers to plaintiffs' opening brief, and any citations to amicus briefs use an abbreviated form of the name of the party listed first on the brief.

Plaintiffs' approach to statutory interpretation is not legitimate. This Court "assume[s] that the legislative purpose is expressed by the ordinary meaning of the words used," *United States* v. *James*, 478 U.S. 597, 604 (1986); is "not willing to narrow the plain meaning of * * * [a] statute on the basis of a gestalt judgment as to what Congress probably intended," *Garcia* v. *United States*, 469 U.S. 70, 78 (1984); and will not take the "extraordinary" step of "requir[ing] legislative history to *confirm* the plain meaning of" a statute, *Bourjaily* v. *United States*, 483 U.S. 171, 178 (1987). As the Court has explained, "no legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987) (per curiam).

Plaintiffs focus exclusively on the congressional intent to protect consumers from unsafe and ineffective devices and *completely ignore* the congressional intent to promote availability and innovation of devices by prohibiting state requirements through the preemption provision. Compare Cross-Pet. Br. 2-3, 11 with Pet. Br. 1-10 and U.S. Br. 2. By focusing on only one of Congress's several objectives, plaintiffs entirely disregard the congressional intent to enact a "balanced regulatory proposal," H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976), and thereby overlook the purpose of *the FDCA preemption provision*—enhancement of public health by preventing state regulation from stifling innovation of, and access to, critical medical technologies. See Pet. Br. 1-5, 46-49; PLAC Br. 4-8. The congressional balance of interests is manifest in the language of the preemption provision, which prohibits state device requirements "relat[ing] to * * * safety or effectiveness," even if the state requirements would be "more stringent" than applicable federal requirements. 21 U.S.C. 360k(a)(2), (b)(1).

Plaintiffs not only stress one congressional objective repeatedly to the exclusion of others, but also they overlook the *means* Congress selected to carry out the goal of protecting consumers from unsafe and ineffective devices. Plaintiffs incorrectly imply that the congressional intent to protect consumers necessarily requires compensation through tort remedies. But Congress instead chose to protect consumers by giving the FDA significant new authority to impose substantive safety and effectiveness requirements, remove dangerous devices from the market, and control market entry through premarket clearance processes. See Pet. Br. 5-10. Because the MDA substantially *enhanced* consumer protection by imposing new federal requirements, plaintiffs are simply incorrect in asserting that the statute's preemption of common law claims leaves consumers with less protection than they had before the MDA's enactment.[2]

Even if one were willing to join plaintiffs in speculating what Congress *could* or *could not* have intended, there would be no reason to doubt that Congress meant what it said in the encompassing words of the statute, i.e., meant to preempt *all* state "requirements"—including those imposed by the common law—that are "different from, or in addition to," *any* applicable FDCA requirement and that relate to safety or effectiveness *or* to another matter covered by an applicable FDCA requirement. Members of Congress thinking rationally about the *benefits* that thousands of safe and effective medical devices provide millions of consumers—and not just focusing obsessively on the well-

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[2] Attempting to minimize the significance of these comprehensive federal requirements, plaintiffs erroneously suggest (e.g., Cross-Pet Br. 35-36) that devices cleared through the 510(k) process put the public at risk through inadequate premarket scrutiny of safety and effectiveness. This assertion fundamentally contradicts their contention that Congress enacted the MDA as "landmark legislation" addressed solely to consumer protection. In any event, as Medtronic explained in detail in its opening brief, the statute created multiple safeguards applicable to 510(k) devices. See Pet. Br. 8-10, 23-27; see also HIMA Br. 3-22.

publicized problems of a *single* device, the Dalkon Shield—could easily conclude that the best approach to regulation was to concentrate it in one federal agency, capable of considering both costs and benefits, and not to allow states to supplement such intensive federal regulation with additional state "requirements," *especially* not state requirements imposed by ad hoc decisions applying the generalities of the common law to individual circumstances. Members of Congress also easily could be concerned about the effect of state regulation (including application of the common law) on product availability and innovation and on the resources of small medical device manufacturers (which typified the industry in 1976 and still do today). See MDMA Br. 4-7; HIMA Br. 22-29; Ctr. for Patient Adv. Br. 11-23. And the best possible evidence that Congress *did* act on these concerns is the words of the statute.[3]

Furthermore, it certainly is not unusual for Congress to protect the public with comprehensive federal regulation on the one hand while preempting state tort remedies on the other. See, e.g., *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992); *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658 (1993).[4] And this

[3] The presence of an exemption clause (21 U.S.C. 360k(b)) allowing states to supplement federal regulation, *but only when the FDA agrees that the supplemental regulation meets certain standards*, mitigates any possible harshness from the breadth of the basic preemption provision (*id.* § 360k(a)). Cf. Cal. Br. 15-17 (asserting that, under a broad reading of the preemption provision, a "state remains powerless" to protect its own citizens, but *completely ignoring* exemption provision).

[4] This Court's decision in *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), does not warrant a different conclusion. As the opinion makes clear, *id.* at 249-256, and as the Court subsequently has explained, "the decision in *Silkwood* was based in substantial part on legislative history suggesting that Congress did not intend to include in the pre-empted field state tort remedies for radiation-based injuries." *English* v. *General Elec. Co.*, 496 U.S. 72, 86 (1990). Equally inapposite is *United Constr. Workers* v. *Laburnum Constr. Corp.*, 347 U.S. 656 (1954). See Nat'l Conf. of State Legis. Br. 6, 27-28; TLPJ Br. 16-17; ATLA Br. 14, 24; PLC-MDL Br. 5-6, 19. This Court's resolution of the question presented in *Laburnum*—whether Congress's

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Court often has found preemption "even when the state action purported to authorize a remedy unavailable under the federal provision." *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 55 (1987). At least since *San Diego Building Trades Council* v. *Garmon*, 359 U.S. 236 (1959), the law has been settled that "the States' salutary effort to redress private wrongs or grant compensation for past harm" cannot justify state intrusion into a federal regulatory system, even though "the state remedy ha[s] no federal counterpart." *Id.* at 247; see also *Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 584 (1981) ("A finding that federal law provides a shield for the challenged conduct will almost always leave the state-law violation unredressed."); *Gillespie* v. *United States Steel Corp.*, 379 U.S. 148, 154-155 (1964) (Jones Act preempts state law even though plaintiff had no cause of action under the Act).[5]

(Footnote continued from previous page)

assignment to the NLRB of exclusive jurisdiction over unfair labor practices precluded a common law damages action arising out of conduct that might qualify as such an unfair practice—rested on numerous factors that simply have no application to this case. See 347 U.S. at 664-669 (relying *inter alia* on "the language of the Act," its "legislative history" and prior decisions interpreting the statute as "leav[ing] much to the states.")

[5] In any event, contrary to plaintiffs' assertions, Congress *did* provide a federal remedy to compensate consumers for devices that present an unreasonable health risk because they were not properly designed or manufactured. The statute gives the FDA authority to issue orders requiring device manufacturers to repair the device, replace it with one that conforms to FDCA requirements, or refund its purchase price. This federal remedy also includes "any reasonable and foreseeable expenses." 21 U.S.C. 360h(b)(3). If the FDA does not issue the order on its own initiative, any affected person may petition the agency to take action. 21 C.F.R. 10.25, 10.30. Although the statutory remedy is more limited than tort recovery might offer, the provision of reasonable and foreseeable expenses could include the types of medical expenses that Mrs. Lohr alleges she incurred in this case. Thus, plaintiffs are wrong in asserting that preemption of their tort claims would deny them access to any remedy for a defective device.

Whatever policies and "presumptions" the parties and amici may advance,[6] in the end this case must turn on the plain wording of the statute, which "necessarily contains the best evidence of Congress' pre-emptive intent," *Easterwood*, 507 U.S. at 664. As we now show, the statutory language, as informed by this Court's decisions, demonstrates that the FDCA preempts plaintiffs' claims for failure to warn and defective manufacture.

SUMMARY OF ARGUMENT

I. Under this Court's opinion in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), common law damages actions establish state "requirements" subject to preemption under the MDA. Plaintiffs attempt to distinguish *Cipollone*, but ultimately they merely re-argue issues the Court already has resolved against them.

The language of the FDCA preemption provision encompasses state common law claims. The Court should reject—as the Solicitor General does—plaintiffs' argument that the use of the term "requirement" three times in the preemption provision preserves common law claims. Although modifiers indicate that the two references to federal requirements only concern positive law, there are no similar modifiers that limit state requirements to positive law. The statutory language also does not support plaintiffs' argument restricting preemption only to those state requirements that apply exclusively to devices.

In addition, the Court should reject—again, as the Solicitor General does—plaintiffs' argument that common law claims are not subject to the statutory exemption provision, and therefore are outside the scope of the preemption provision. The exemption provision does cover common law claims. Even if it did not, there is no basis in the statute for concluding that the absence of an exemption affects the scope of preemption under the statute. Furthermore, the limited "savings clause" set forth at 21 U.S.C. 360h(d) does not contemplate preservation of tort claims, because it easily can be read to refer to other types of state-law liability.

[6] Compare Nat'l Conf. of State Legis. Br. 6-7 (strong presumption against preemption) with GM Br. 19-23 (no presumption against preemption except in cases of "field" preemption).

II. The FDCA preempts plaintiffs' failure-to-warn claims. The FDCA establishes significant federal requirements governing product warnings through the 510(k) process, the prescription device labeling regulation, post-market warning requirements, and the FDCA's general misbranding provisions. These requirements have preemptive effect, because they are "applicable to the device" within the meaning of the FDCA preemption provision. The Court should reject plaintiffs' argument that these requirements are not preemptive because they are not "device-specific"; plaintiffs' construction has no basis in the statutory language.

Plaintiffs' claims for failure to warn are preempted because they would establish state duties "different from, or in addition to," the federal prescription device labeling regulation, the 510(k) requirements, and the general misbranding provisions of the FDCA. The premise of these claims is that warnings that comply with these federal requirements are inadequate, and that state common law requires different and additional warnings. In addition, the state duties that would be imposed by plaintiffs' claims are not the same as the standards imposed by the federal requirements, and that fact alone is enough to preempt them.

III. The FDCA also preempts plaintiffs' defective manufacturing claims. The FDA's Good Manufacturing Practice ("GMP") regulations and the 510(k) process impose significant federal manufacturing requirements. These requirements have preemptive effect, because they are "applicable to the device" within the meaning of Section 360k(a).

Plaintiffs' claims are preempted because they would establish state duties "different from, or in addition to," the GMP regulations and 510(k) requirements. The premise of these

claims is that a manufacturing process that complies with these federal requirements is inadequate, and that state common law requires a different process. In addition, the state duties that would be imposed by plaintiffs' claims are not the same as the standards imposed by the federal requirements, and that is enough to preempt the claims.

IV. The FDCA also preempts plaintiffs' claims to the extent that they rely on federal standards. According to plaintiffs, identical state and federal requirements are not "different from, or in addition to," each other. That interpretation, however, is flawed: it reads the statute as if it preempts only "different" state requirements, and thus renders completely superfluous the phrase "in addition to." Moreover, plaintiffs' interpretation is inconsistent with the structure and legislative history of the MDA and the congressional intent to establish uniform device requirements. Equally mistaken is the Solicitor General's submission that "remedies" do not constitute "requirements." Contrary to the government's assertion, the FDA has *not* "consistently, and reasonably" (U.S. Br. 9-10) read the term "requirement" to exclude remedies. In fact, the FDA on several occasions has indicated that "remedies" *are* a species of state "requirements."

ARGUMENT

The first and longest argument in plaintiffs' opening brief (Cross-Pet. Br. 14-34)—which also is the *sole* argument made by most of plaintiffs' amici—is a sweeping assertion that the FDCA preempts *no common law damages claims at all*. The Solicitor General disagrees, as do the FDA and nine courts of appeals. U.S. Br. 15-19 & n.12; Pet. Br. 37 n.19.[7] We show in Point I below that both this Court's *Cipollone* decision and the language and structure of the statute foreclose plaintiffs'

[7] One court of appeals agrees with plaintiffs. *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) (Ferguson, J.); see also *id.* at 1460-1462 (Reinhardt, J., concurring).

argument. Plaintiffs' next argument is that the common law claims preempted by the FDCA do not include the failure-to-warn and defective manufacturing claims in *this* case. Cross-Pet. Br. 34-45. We show in Points II (failure to warn) and III (defective manufacturing) that plaintiffs are wrong; the court of appeals correctly held these claims preempted.

Finally, plaintiffs argue briefly that they may escape preemption by recasting their state-law claims as claims relying on federal standards. Cross-Pet. Br. 45-47. A cryptic passage in the Solicitor General's brief likewise claims that the FDA has consistently interpreted the term "requirement" in Section 521(a) not to preempt state tort remedies—even though that interpretation was newly conceived for this case. We show in Point IV below that acceptance of these arguments would be inconsistent with Congress's carefully crafted remedial scheme and the language and purpose of the statute.[8]

I. COMMON LAW CLAIMS ESTABLISH STATE REQUIREMENTS SUBJECT TO PREEMPTION UNDER THE FDCA

A. This Court Should Reject Plaintiffs' Re-Argument of Issues Resolved in *Cipollone*

Medtronic's opening brief explains that under the holding in *Cipollone*, 505 U.S. 504 (1992), plaintiffs' claims would establish state "requirements" within the meaning of the FDCA preemption provision. See Pet. Br. 36-39. Plaintiffs understandably seek to distinguish *Cipollone*, but, as the Solicitor General

[8] Plaintiffs and their amici rely extensively on a recent law review article that argues that the FDCA does not preempt common law claims. See Robert S. Adler & Richard A. Mann, *Preemption & Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895 (1994). For a point-by-point response to that article, see Mark Herrmann & Geoffrey J. Ritts, *Preemption & Medical Devices: A Response To Adler & Mann*, 51 Food & Drug L.J. 1, 8-19 (1996) (page proof copies of which have been lodged with the Clerk).

explains, their arguments are "difficult to square with" that decision. U.S. Br. 15-19.

Plaintiffs assert that common law claims merely require manufacturers to compensate plaintiffs and "do not require manufacturers to take any action with respect to a device." Cross-Pet. Br. 20; see also ATLA Br. 5-10. That assertion contradicts the fundamental premise of the *Cipollone* holding, which is that common law regulates conduct in the same manner as statutes or regulations. As Justice Stevens explained in his plurality opinion, common law claims establish state "requirements" because "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." 505 U.S. at 521 (quoting *Garmon*, 359 U.S. at 247).[9]

Cipollone also disposes of plaintiffs' argument that there can be no preemption of their claims without an explicit statutory reference to extinguishment of tort remedies, Cross-Pet. Br. 18, 31. The Cigarette Act at issue in *Cipollone* contained no explicit reference to common law claims, yet the Court affirmed their preemption. See also *Easterwood*, 507 U.S. at 664 (affirming preemption of common law claims without explicit reference to such claims in express preemption provision).

Cipollone further forecloses plaintiffs' argument that their claims are preserved because they are not "establish[ed] or continue[d] in effect" by a state, Cross-Pet. Br. 21-22. There is no principled distinction between the terms of the FDCA and the language of the Cigarette Act at issue in *Cipollone*, which pre-

[9] The Court's analysis in *Cipollone* was consistent with earlier cases recognizing that exposure to common law claims compels manufacturers to change their conduct to avoid future liability. See, e.g., *International Paper Co.* v. *Ouellete*, 479 U.S. 481, 495 (1987); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981).

empted requirements "imposed" under state law, *Cipollone*, 505 U.S. at 515. Similarly, this Court held in *Easterwood* that common law claims were preempted under a Federal Railroad Safety Act provision barring "[a] State" from "adopt[ing] or continu[ing] in force" certain railroad safety standards. 507 U.S. at 662 & n.2.

Finally, *Cipollone* rejects plaintiffs' assertion that the statute preserves their claims because its legislative history does not explicitly refer to preemption of tort actions, Cross-Pet. Br. 30.[10] In *Cipollone*, this Court affirmed preemption of common law personal injury claims, even though portions of the Cigarette Act's legislative history suggested that "Congress was primarily concerned with positive enactments by States and localities," 505 U.S. at 521 (opinion of Stevens, J.), and there was no explicit reference in the legislative history to common law damages actions, *id.* at 540 (opinion of Blackmun, J.). Because the Act's *language* "plainly reache[d] beyond" positive enactments, 505 U.S. at 521 (opinion of Stevens, J.), the Court held that common law claims were subject to preemption. Similarly, in *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 385 n.2 (1992), this Court held that the Airline Deregulation Act preempted state advertising standards, even though the statute's legislative history contained no statements specifically ad-

[10] There is no claim that the legislative history contains statements *negating* the conclusion that tort actions are preempted. Instead, plaintiffs explicitly rely on "[t]he legislative history's *silence* on preemption of damages remedies." Cross-Pet. Br. 30 (emphasis added). Some of plaintiffs' amici do purport to find evidence in individual legislators' statements or in committee reports that the FDCA does not preempt tort claims (e.g., TLPJ Br. 7-8 & nn.5-6; AARP Br. 4 n.1, 19 n.10), but they rely on materials associated with *subsequent* legislation, or even subsequent congressional inaction. Such materials have no probative value at all. See *Brown* v. *Gardner*, 115 S. Ct. 552, 557 (1994); *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 114 S. Ct. 1439, 1453 (1994); *Pension Benefit Guaranty Corp.* v. *LTV Corp.*, 496 U.S. 633, 650 (1990); *Patterson* v. *McLean Credit Union*, 491 U.S. 164, 175 n.1 (1989).

dressing state regulation of advertising. See also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 n.2 (1990) (statute can have effects not explicitly mentioned in its legislative history). In the present case, the Court also should conclude that the statutory language mandates preemption despite the silence of the legislative history.

B. The Language of the FDCA Preemption Provision Encompasses Common Law Claims

1. The Preemption Provision's Use of the Term "Requirement" Three Times Does Not Exclude State Common Law Claims

Plaintiffs contend that the term "requirement" in the FDCA preemption provision necessarily means the same thing each of the three times it appears. Because two of the three references are to federal requirements imposed solely pursuant to statute or regulation, plaintiffs argue that the single reference to state requirements is similarly limited, excluding common law claims. Cross-Pet. Br. 18-19. As the Solicitor General explains, plaintiffs' argument does not withstand scrutiny. U.S. Br. 17.

Like the Cigarette Act in *Cipollone*, the FDCA defines preempted state requirements according to their content and does not distinguish between common law and positive enactments. See *Cipollone*, 505 U.S. at 515. State requirements are preempted if they "*relate*[] [i] *to the safety or effectiveness of the device or* [ii] *to any other matter included in a requirement applicable to the device*" under the FDCA and fit the other terms of the preemption provision. 21 U.S.C. 360k(a)(2) (emphasis added). In contrast, the FDCA defines preemptive *federal* requirements with modifiers indicating their statutory and regulatory *source* rather than their subject matter. Thus, the FDCA describes a preemptive requirement as "*any requirement applicable under this chapter to the device*." *Id.* § 360k(a)(1) (emphasis added). As the Solicitor General notes, the obvious conclusion that federal requirements derive from regulations and statutory provisions rather than common law does not extend to the state requirements, because the FDCA does not limit state requirements with any modifier referring to positive law. U.S. Br. 17; see also Herrmann & Ritts, *supra*, 51 Food & Drug L.J. at 8-9.

Finally, plaintiffs' construction of the FDCA preemption provision would lead to absurd results. Their distinction between common law and positive law is particularly untenable in a state like Florida, which has adopted common law doctrines *by statute*.[11] Furthermore, if preempted state requirements were limited to positive law, the FDCA would prohibit personal injury claims in states that have codified their tort doctrines[12] but preserve claims in states that have not. Plaintiffs' construction of the statute would establish an irrational pattern of liability exposure from state to state, undermining the congressional intent to establish uniform nationwide requirements for medical devices. See Pet. Br. 4-5. This Court should conclude that the FDCA's language does not support plaintiffs' untenable distinction between common law and positive law.

2. The FDCA Does Not Restrict Preemption to State Requirements That Apply Exclusively to Devices

Relying on an FDA regulation, plaintiffs assert that Section 360k(a) does not apply to common law claims because it pro-

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[11] See, e.g., *Coastal Petroleum Co.* v. *American Cyanamid Co.*, 492 So. 2d 339, 347 (Fla. 1986) ("In 1819, the territorial legislature of Florida adopted a statute declaring the common law of England to be of force in Florida. The statute, in modified form but unchanged as to substance, is still in effect * * *.") (Boyd, C.J., dissenting), cert. denied, 479 U.S. 1065 (1987).

[12] See, e.g., Conn. Gen. Stat. Ann. §§ 52-572m to 52-572q (West 1991); Ind. Code Ann. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996); La. Rev. Stat. Ann. §§ 9:2800.51 to 9:2800.59 (West 1991); Me. Rev. Stat. Ann. tit. 14, § 221 (West 1980); Miss. Code Ann. § 11-1-63 (Supp. 1994); Mont. Code Ann. § 27-1-719 (1993); N.C. Gen. Stat. §§ 99B-1 to 99B-11 (Michie 1995); Ohio Rev. Code Ann. §§ 2307.71 to 2307.80 (Baldwin 1996); S.C. Code Ann. §§ 15-73-10 to 15-73-30 (Law. Co-op. 1993).

hibits only those state requirements that apply exclusively to devices. Cross-Pet. Br. 19-21. As the Solicitor General explains, however, plaintiffs' argument is "strained as a grammatical matter," because the statutory language encompasses state requirements "of general applicability" such as tort duties. U.S. Br. 17-18. The Solicitor General's brief, in fact, flatly contradicts the FDA's previous interpretation. Compare U.S. Br. 18 (the language of the preemption provision "suggests that such a [preempted state] 'requirement' may be one *of general applicability*") (emphasis added) with 21 C.F.R. 808.1(d)(1) ("Section 521(a) does not preempt State or local requirements *of general applicability* where the purpose of the requirement relates * * * to *other products in addition to devices* * * *.") (emphasis added).[13]

Plaintiffs argue that claims asserting violations of generally applicable tort duties are not preempted because, under the statute, "only state *requirements* '*with respect to a device*' are candidates for preemption." Cross-Pet. Br. 19-20 (emphasis added). But plaintiffs' construction changes the order of words in the statutory language, thereby altering their meaning. Section 360k(a) provides that state requirements may not be "*establish[ed] or continue[d] in effect with respect to a device*" (emphasis added). Thus, the phrase "with respect to a device" modifies the verbs "establish" and "continue in effect" rather than the noun "requirement." As the Solicitor General notes, the statutory language indicates that the requirements could be established or continued in effect in other contexts not involving

[13] The Solicitor General's abandonment of the FDA's gloss on the statute wisely anticipated this Court's decision in *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996), which points out (slip op. 15) that "a statute may specifically relate to more than one thing" and that Congress's preemptive intent is not to be disregarded just because a statute relates to other things in addition to the subject cited in the statute.

devices; requirements therefore need not apply exclusively to devices to be preempted. U.S. Br. 18.[14]

Plaintiffs' interpretation also would "creat[e] an utterly irrational loophole." *Morales*, 504 U.S. at 386. For example, under their interpretation, the FDCA would preserve a general state product warning or manufacturing requirement not directed exclusively to devices, even if it directly conflicted with federal device warning or manufacturing requirements. But, as this Court noted in *Morales*, "there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute." *Ibid.* Plaintiffs' construction also would allow states to avoid preemption by the simple expedient of structuring their medical device statutes and regulations to apply to one or two other products (e.g., drugs) in addition to devices. Plaintiffs fail to explain why Congress would have wanted a regime that tolerates such conflicting state regulation and permits such easy circumvention of the preemption clause.[15] See also PLAC Br. 16-20.

[14] See also *Cipollone*, 505 U.S. at 515 (affirming preemption of claims under generally applicable common law doctrines as requirements *imposed* under state law *with respect to* the advertising or promotion of any cigarettes); *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817, 821 (1995) (affirming preemption of claims under generally applicable consumer fraud statute as state law *relating to* rates, routes, or services of any air carrier); *Morales*, 504 U.S. at 386 (preempting application of general consumer protection statutes to air carrier advertising).

[15] The Court should reject plaintiffs' assertion that it should defer to the agency pronouncements they cite to support their construction of the statute. Deference to agency interpretations is not appropriate in cases such as this, in which the intent of Congress is clear in the statute. *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (1984). Furthermore, the Solicitor General has resolved any doubt about the propriety of deference by abandoning the pronouncements cited by plaintiffs. The Solicitor General agrees with Medtronic that generally applicable common

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C. Other Provisions of the FDCA Support Preemption of Common Law Claims

Citing 21 U.S.C. 360k(b), which grants the FDA authority to exempt state requirements from preemption, plaintiffs argue that Congress could not have intended the exemption provision to apply to state requirements established through common law claims, because it is not practically feasible to grant exemptions for such requirements. They further reason that, if the exemption provision in subsection (b) does not encompass common law claims, neither does the preemption provision in subsection (a). Cross-Pet. Br. 24-27. As the Solicitor General explains, however, plaintiffs' assumption and conclusion are both invalid. See U.S. Br. 18-19.

Congress said nothing in subsection (b) to exclude common law duties. Medtronic agrees that it might be very difficult for a state to demonstrate that its common law duties meet the standards of subsection (b) and warrant an exemption. But that *practical* difficulty does not exclude common law duties from the broad statutory language. See U.S. Br. 18.[16]

Furthermore, even if subsection (b) excluded common law claims entirely, as plaintiffs suggest, there is nothing in the statute indicating that Congress intended to ensure the availability of an exemption for every type of requirement subject to preemption under subsection (a). As the Solicitor General notes, Congress may well have contemplated that the difficulties of granting an exemption for common law requirements exclude

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law duties are preempted if they are different from, or in addition to, applicable FDCA requirements. U.S. Br. 10-12, 15-19.

[16] It may be relatively rare for a state to apply for an exemption for common law doctrines, as plaintiffs note. Cross-Pet. Br. 24-27. Nonetheless, the FDA has never taken the position that exemptions for common law duties are unavailable, "and the FDA does not do so here." U.S. Br. 18 n.13.

them from subsection (b), even though they are subject to preemption under subsection (a). U.S. Br. 18-19.[17]

The Court also should reject plaintiffs' argument that 21 U.S.C. 360h contemplates preservation of tort claims against device manufacturers. See Cross-Pet. Br. 27-28. That section gives the FDA broad authority to issue administrative orders to remedy unreasonable public health risks created by medical devices. Section 360h(d) also states that compliance with one of these remedial orders does not affect other liability under state or federal law:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

This reference to federal or state liability is not necessarily a reference to personal injury tort claims, and a general reference to "liability" certainly does not indicate that all tort claims are beyond the reach of the preemption provision. Section 360h(d)

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[17] Congress's desire not to hamper the innovation of life-saving medical technologies, or to burden unduly the small manufacturers that make up this industry, is manifest in the overall design and structure of Section 360k, which includes both a very broad preemption provision and an exemption provision that grants discretion to the expert federal regulator to make exceptions if certain statutory criteria are satisfied. That design largely removes the onus from manufacturers to determine which state requirements are preempted, and places the burden instead on states to seek exemptions in cases of doubt. That structure also permits a single national decisionmaker—the FDA—to assess the incremental effect of multiple or successive exemptions on the cost and availability of particular devices. And it vests in the expert agency the authority—at least when the statutory criteria for an exemption are satisfied—to assess a state's assertions about the need for "different" or "addition[al]" safety and effectiveness requirements, as well as to weigh the benefits of such requirements against the burdens they would impose.

can easily be read as having nothing to do with tort liability, referring instead to state contractual liability for economic loss in disputes between device manufacturers, importers, distributors, and retailers arising from issuance of an agency remedial order.[18] The clause also could apply to state tort duties (whether or not codified by statute) that the FDA exempts from preemption. See pp. 16-17 *supra*. These readings of the statute respect the broad language of the FDCA preemption provision, consistent with this Court's decisions establishing that savings clauses "cannot in reason be construed as continuing * * * a common law right, the continued existence of which would be absolutely inconsistent with the provisions of [an] act." *Texas & Pac. Ry.* v. *Abilene Cotton Oil Co.*, 204 U.S. 426, 446 (1907); see also *Morales*, 504 U.S. at 384-385; GM Br. 16-17; Herrmann & Ritts, *supra*, 51 Food & Drug L.J. at 10-12.

II. THE FDCA PREEMPTS PLAINTIFFS' FAILURE-TO-WARN CLAIMS

Relying on different rationales, plaintiffs, their amici, and the Solicitor General all argue that, even if state "requirements" covered by Section 360k(a) can include common law claims, the failure-to-warn and defective manufacturing claims in this case are not preempted. Plaintiffs and their amici rest almost entirely on the notion (founded in an FDA regulation and *not* in the statute itself) that only "device-specific and subject-specific" federal requirements have any preemptive effect. Cross-Pet. Br. 39-44; see Calif. Br. 11-17; PLC-MDL Br. 7-14. The Solicitor General *rejects* that argument (U.S. Br. 18) but presents rea-

[18] For example, if the FDA orders a wholesale distributor to repair a retailer's shipment of defective devices under Section 360h(b), the retailer may still wish to sue the distributor for breach of contract. Section 360h(d) would allow the suit to proceed, with the value of the repaired devices being subtracted from any additional damages recovered. Cf. *Wolens*, 115 S. Ct. at 826 (claims under Illinois Consumer Fraud Act preempted, but savings clause preserved contractual remedies).

sons—which are rather opaque—why he believes plaintiffs' claims survive preemption nevertheless. U.S. Br. 22-28.

The reason for this disarray of rationales is not hard to fathom. Plaintiffs, their amici, and the Solicitor General are not willing to focus on the one sure guide to statutory interpretation: the words that Congress enacted. Attention to those simple words makes it quite easy to apply the preemption provision to this case—and to conclude that plaintiffs' claims are preempted.

The FDCA preemption provision is written in the following broad words:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, *any requirement applicable under this chapter to the device*, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a) (emphasis added). It is beyond rational debate—although both plaintiffs (Cross-Pet. Br. 34-38) and the Solicitor General (U.S. Br. 19-21, 22 n.16) continue to debate the point—that *any* FDCA requirement applicable to the device has preemptive effect. Thus, when the Solicitor General asserts that the 510(k) process has no preemptive effect at all because it "does not reflect a determination by the FDA that the device is safe and effective, much less a specific determination that the device's design is required to ensure its safety and effectiveness," U.S. Br. 19, he answers a question that the statute does not ask.[19] This Court is not called upon to decide how far the

[19] "No answer is what the wrong question begets * * *." Alexander Bickel, *The Least Dangerous Branch* 103 (1962). The Eleventh Circuit made

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510(k) process goes to ensure safety and effectiveness, but rather only whether it imposes a "requirement applicable under this chapter to the device."[20] And there is no possible doubt that it does, for reasons explained in our opening brief (Pet. Br. 30-36).[21]

The 510(k) requirements are not the only federal requirements that apply to the Model 4011 with preemptive effect. As we will now explain in detail, *several* federal "requirements" are preemptive, and plaintiffs' claims would establish state requirements that are "different from, or in addition to," those federal requirements and that relate to safety and effectiveness and other matters covered by the FDCA.

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the same error (Pet. App. 26a-27a), although it correctly held that plaintiffs' failure-to-warn and defective manufacturing claims are preempted.

[20] Even the preempted *state* requirement need only "relate[] to" safety or effectiveness (or another matter included in an applicable FDCA requirement). 21 U.S.C. 360k(a)(2). Congress did not apply even *that* modest limitation (see *Barnett Bank*, slip op. 12) to the *federal* requirement. See *id.* § 360k(a)(1). There is no textual basis for the Solicitor General's bold assertion that a preemptive federal requirement must not only relate to, but also *ensure*, safety and effectiveness. In any event, as Medtronic explained in its opening brief, the 510(k) process *does* impose significant safety and effectiveness requirements on the Model 4011. See Pet. Br. 19-30.

[21] The Solicitor General *himself* recognizes that anything referred to in other sections of the FDCA as a "requirement" must be a requirement for purposes of Section 360k(a), yet he ignores the logical consequence of that argument, which is that requirements imposed under the 510(k) process must be preemptive. Compare U.S. Br. 24 n.19 (conceding "that the GMPs impose 'requirement[s]' within the meaning of Section [360k](a)" because other sections of the FDCA refer to them as imposing "requirements") with Pet. Br. 31-32 (arguing, in a passage that the Solicitor General ignores, that Section 510(k) imposes "requirements" within the meaning of Section 360k(a) because other sections of the FDCA refer to it as imposing "requirements").

A. The FDCA Establishes Substantial Requirements for Product Warnings Concerning the Model 4011

1. The 510(k) Process Imposes Substantial Requirements Concerning Labeling Warnings

The 510(k) premarket clearance process imposes substantial requirements concerning labeling warnings for prescription devices such as the Model 4011.[22] It prevents marketing without FDA clearance, requires submission of significant information about the device for FDA review, and bars significant changes without further FDA clearance. See Pet. Br. 19-30. All of these requirements apply with full force to the Model 4011's labeling.[23]

Manufacturers must submit proposed labeling for agency review to obtain 510(k) clearance. 21 C.F.R. 807.87(e).[24] The FDA reviews the labeling as part of its determination of sub-

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[22] The FDCA distinguishes the term "label" from the broader term "labeling." "Label" means "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. 321(k). "Labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). Under the FDCA, "labeling" includes a broad variety of product literature (including technical manuals explaining product use and promotional materials), even if they do not physically accompany distribution of the device. See *Kordel* v. *United States*, 335 U.S. 345 (1948).

[23] Plaintiffs fail to mention most of these requirements and incorrectly characterize the 510(k) process as a notification provision. See Cross-Pet. Br. 5, 34-35.

[24] Plaintiffs cite a GAO report for the proposition that the FDA may clear devices for marketing without submission of labeling. Cross-Pet. Br. 42. The report does not support plaintiffs' assertion, because it indicates only that some 510(k) applications lack labeling when the FDA initially *receives* them. U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved 62 (GAO/PEMD-88-14, Aug. 1988). The FDA's authority to ask for additional information before granting premarket clearance (see 21 C.F.R. 807.87(k)) resolves such deficiencies. In any event, Medtronic did submit labeling in its 510(k) application concerning the Model 4011.

stantial equivalence. See, e.g., FDA Draft Guidance for Format and Content for Premarket Notification 510(k) (Mar. 23, 1994) at A-8, A-13 ("Substantial equivalence is to be established with respect to, but not limited to, intended use, design, energy used/delivered, materials, performance, safety, effectiveness, *labeling*, and other applicable characteristics.") (emphasis added). For devices in which the inclusion of specific warnings is critical to a finding of substantial equivalence, the FDA's review "includes an evaluation of the compliance of the proposed labeling, or portions thereof, with applicable requirements under 21 C.F.R. Part[] 801." Device Labeling Guidance, FDA General Program Memorandum #G91-1 (Mar. 8, 1991) at 2. The 510(k) review also may lead the agency to *prohibit* certain warnings that it deems inappropriate. See, e.g., FDA 510(k) Clearance Letter K914966 (May 13, 1992) (barring warnings regarding use of bone screw in the spine).

After marketing begins, the 510(k) requirements also bar manufacturers from changing labeling warnings in a manner that could affect safety or effectiveness of the device significantly unless the FDA clears the labeling changes through another 510(k) review. See 21 C.F.R. 807.81(a)(3)(i). For example, 510(k) review is required for labeling changes that arise from significant new issues of safety or effectiveness not evident at the time of initial FDA clearance. If the manufacturer makes significant labeling changes without FDA clearance, the agency may initiate an enforcement action to stop distribution of the device. Cf. Complaint, *United States* v. *11,307 Boxes*, No. 93-574 (S.D. Fla. filed Mar. 24, 1993) (seizure complaint alleging significant changes of labeling in violation of 21 C.F.R. 807.81(a)(3)).

2. The Prescription Device Labeling Regulation Imposes Substantial Warning Requirements

The FDA's prescription device labeling regulation, 21 C.F.R. 801.109, imposes substantial requirements on the Model 4011, contrary to plaintiffs' suggestion that it does "little more

than tell manufacturers to list * * * warnings * * * and the like." Cross-Pet. Br. 43. The regulation requires that the labeling disclose information concerning use of the prescription device, "including indications, effects, routes, methods, and frequency and duration of administration." 21 C.F.R. 801.109(c). In addition, the regulation requires the manufacturer to include the following warnings on the labeling so that physicians are adequately informed of

> any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented.

Ibid. The regulation does, however, allow manufacturers to omit those directions, hazards, and warnings that are "commonly known to practitioners licensed by law to use the device." *Ibid.*

Furthermore, under the regulation, devices such as the Model 4011 may be sold "only to or on the prescription or other order of [a] practitioner for use in the course of his professional practice." 21 C.F.R. 801.109(a)(2); R1-37-Exh.1, at 3-4. By definition, prescription devices are those for which there cannot be adequate directions for use by laypersons. 21 C.F.R. 801.109. To ensure appropriate physician oversight, the regulation requires manufacturers to include a legend restricting the device "to sale by or on the order of a physician." 21 C.F.R. 801.109(b)(1); R1-37-Exh.1, at 3.

The FDA's enforcement activities underscore the significance of these requirements. As the Eleventh Circuit noted, "the FDA's record of taking action against mislabeled devices forecloses the argument that the Act's labeling requirements lack substantive 'bite.' " Pet. App. 33a.; see, e.g., *United States* v. *An Article of Device*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984) (seizure action for violation of 21 C.F.R. 801.109); *United States* v. *Articles of Device*, 426 F. Supp. 366 (W.D. Pa. 1977) (same).

3. The FDCA and Related Regulations Give the FDA Substantial Authority to Require Additional Warnings After Marketing Begins and Prohibit Distribution of Devices with Inadequate Warnings

Although the FDA has not required warnings for the Model 4011 beyond those in the labeling cleared through the 510(k) process, the agency does have substantial authority to require additional warnings once marketing begins. Under 21 C.F.R. 895.25, the FDA may require manufacturers to change a device's labeling to contain statements, notices, or warnings if the device presents unreasonable public health risks. 21 C.F.R. 895.25(a), (b). The FDA has authority to dictate when the labeling change must occur and how long it must last. *Id.* § 895.25(a)(3), (b). If the manufacturer does not carry out the required change in labeling, the FDA has authority to initiate a proceeding to ban the device, 21 U.S.C. 360f; 21 C.F.R. 895.25(d), or take the device off the market through its other broad remedial powers. See, e.g., 21 U.S.C. 360h(e) (cease and desist authority), 334 (seizure authority). The FDA also has power to require manufacturers to issue notifications (separate and apart from any labeling) warning the public about significant health risks it detects through a variety of sources, including manufacturers' mandatory reports of device malfunctions, serious injuries, and deaths. See 21 U.S.C. 360h(a), (e), 360i.

The FDCA also establishes general prohibitions on distribution of devices rendered unsafe by inadequate warnings. A device is "misbranded" under the statute if the warnings in its labeling are not adequate such that the device may be dangerous to health or if use in accordance with the labeling renders it dangerous to health. 21 U.S.C. 352(f)(2), 352(j). A device also is misbranded if its labeling is "false or misleading" because it omits material warnings. 21 U.S.C. 352(a), 321(n). Manufacturers of misbranded devices are subject to criminal prosecution and actions for seizure, injunction, and civil penalties, among other sanctions. See *id.* §§ 331-334.

B. The Federal Warning Requirements Have Preemptive Effect Because They Are "Applicable to the Device"

"[A]ny requirement applicable under [the FDCA] to the device" has preemptive effect. 21 U.S.C. 360k(a)(1). The plain meaning of that language encompasses all of the federal warning requirements described above. In addition, two other sections characterize the 510(k) requirements as "appl[icable] to the device" (see Pet. Br. 30-32). One of those other sections also characterizes the prescription device labeling regulation and general misbranding provisions as federal requirements "appl[icable] to the device." 21 U.S.C. 360j(a).[25] These federal requirements are therefore preemptive.

Rather than analyzing whether the federal warning requirements are "applicable to the device," as the statute mandates, plaintiffs examine whether they apply *exclusively* to a *single* type of device; under plaintiffs' construction of the statute, only "device-specific" requirements are preemptive. Cross-Pet. Br. 39-42; see also, e.g., Calif. Br. 11-17; PLC-MDL Br. 7-14. But nothing in the language of the preemption provision limits the phrase "any requirement applicable under [the FDCA] to the device" to those requirements that apply exclusively to a single type of device. The court of appeals correctly held that the language of Section 360k(a) "does not suggest that the requirements themselves must mention the particular device in question" in order to have preemptive effect. Pet. App. 19a.[26]

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[25] Section 360j(a) unequivocally establishes that the requirements of Section 502 of the FDCA are applicable to the device unless the FDA changes their applicability or other statutory provisions not relevant to this case conflict with them. The general misbranding provisions are set forth in Section 502 of the FDCA, 21 U.S.C. 352, and the prescription device labeling regulation was promulgated under FDCA § 502(f)(1), 21 U.S.C. 352(f)(1). See 21 C.F.R. 801.109.

[26] Plaintiffs cite the Fifth Circuit's decision in *Moore* v. *Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), for the proposition that federal

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Furthermore, plaintiffs' construction of the preemption provision is inconsistent with the congressional intent to enact a "general prohibition on non-Federal regulation." H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). If preemption were limited to device-specific federal requirements, relatively trivial conflicts between federal and state law (relating only to a single device) would be prohibited, while the statute would leave intact significant broad-based conflicts (relating to numerous devices). For example, federal warning requirements uniquely applicable to pacemaker leads would preempt state regulations imposing different warning requirements, yet federal warning requirements governing broad categories of devices would not preempt similarly broad state laws. Indeed, because there are fewer than two dozen substantive device-specific FDA regulations, and only one device-specific requirement in the statute, plaintiffs' interpretation would wholly eviscerate the FDCA preemption provision.

In addition, plaintiffs' interpretation would make preemption turn on whether the applicable federal regulation explicitly refers to the device at issue—an absurd result with no support in the statutory language. Plaintiffs' interpretation would severely handicap the FDA in promulgating a preemptive regulation, which would need to list every device to which it applied, even if it affected thousands of devices.

Lacking support for their position in the statutory language, plaintiffs retreat to FDA interpretations to justify their construction of the FDCA preemption provision. But the Solicitor General indicates that federal requirements *need not* be device-

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requirements do not preempt state law unless they are device-specific. See Cross-Pet. Br. 14, 31, 43. But the Fifth Circuit has rejected the *Moore* holding, stating that, "since *Moore*, it has become clear that these regulations need *not be device-specific*; they need only apply generally to the device at issue" to preempt state law. *Feldt* v. *Mentor Corp.*, 61 F.3d 431, 436 (5th Cir. 1995) (emphasis added).

specific to be preemptive. The Solicitor General's brief does not even *refer to* the agency interpretations that are the premise for plaintiffs' argument and concedes that the GMP regulations, which apply to thousands of devices, are federal "requirements" under the FDCA preemption provision. See U.S. Br. 24 n.19, 25 n.20.

Although the Solicitor General correctly refutes plaintiffs' analysis, he nonetheless joins their conclusion that there are no preemptive federal requirements applicable to plaintiffs' failure-to-warn claim. U.S. Br. 27-28. The Solicitor General asserts that the 510(k) requirements are not preemptive because they do not reflect a "determination" that the device is safe and effective or an "approval" of the adequacy of the device's labeling (U.S. Br. 19-20, 28). As we have explained (pp. 19-20, *supra*), however, that approach lacks *any* basis in statutory text. And the Solicitor General is silent on the question whether the general misbranding provisions of the FDCA are federal "requirements" within the meaning of Section 360k(a), and he does not even refer to the prescription device labeling regulation, which the Eleventh Circuit relied on as the sole basis for affirming preemption of plaintiffs' claims. U.S. Br. 27-28; see Pet. App. 32a-33a. The Solicitor General simply has not asked the right question, and there is no reason for the Court to accept his analysis.

C. Plaintiffs' Failure-to-Warn Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011

Because common law claims establish state "requirements" potentially subject to preemption, and "any" applicable FDCA requirement can have preemptive effect, all that is left for plaintiff to argue is that their tort claims would not impose requirements "different from, or in addition to," the applicable FDCA "requirement[s]" such as the warning requirements

described above.[27] But the failure-to-warn claims *would* impose different and additional requirements.

Plaintiffs' first theory of liability is that Medtronic gave inadequate warnings to Mrs. Lohr (as distinguished from her physician). R1-3-2; Cross-Pet. Br. 9.[28] The claims alleging failure to warn Mrs. Lohr are preempted, because *any* state-law requirement to warn lay users is "different from, or in addition to," the prescription device labeling regulation. The FDA's regulation defines the Model 4011 as a prescription device—whose distribution is prohibited without a prescription—precisely because adequate directions for lay use are *not possible to prepare* and laypersons cannot adequately understand the risks of its use, regardless of the warnings issued. See 21 C.F.R. 801.109. Yet plaintiffs' claim is that Medtronic should have provided additional warnings directly to Mrs. Lohr. The claim is preempted because it would establish a state requirement "different from, or in addition to," the FDA's regulation, which "exempt[s] [prescription] devices from the requirement that there be directions to a layperson on how to use the product safely." *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13, 18 (1st Cir. 1994).[29]

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[27] Plaintiffs erroneously assert that the state requirements must *conflict* with federal requirements to be preempted. See Cross-Pet. Br. 13.

[28] Although plaintiffs assert a claim for failure to warn Mrs. Lohr, no such claim even exists under Florida law. Florida has adopted the "learned intermediary" doctrine, which holds that any duty to warn about a medical device flows to the doctor and not to the patient. See, e.g., *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511 (S.D. Fla. 1990).

[29] Plaintiffs' claims for failure to warn Mrs. Lohr are preempted for the additional reason that the FDA has the exclusive authority to require notification to patients that they are using a device that puts them at risk. The FDCA accords the FDA discretion, based on its scientific expertise, to determine whether patients should be notified, or whether "notice to such individuals would present a greater danger to the health of such individuals than no such notification." 21 U.S.C. 360h(a). The statute grants the agency this authority, because in a variety of contexts, warning of device risks

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Plaintiffs' second theory of liability is that Medtronic gave inadequate warnings to Mrs. Lohr's physician. The claims asserting this theory also are preempted. First, Florida common law duties to warn the physician are "different from, or in addition to," the requirements of the prescription device labeling regulation. The regulation requires warnings of all "relevant" hazards but also allows omission of warnings if these risks are "commonly known to practitioners licensed by law to use the device." 21 C.F.R. 801.109(c). In contrast, the Florida duty is to provide "fair and adequate" warnings of the device's "inherent * * * dangerous propensities." See, e.g., *Stanley Indus., Inc.* v. *W.M. Barr & Co.*, 784 F. Supp. 1570, 1574 (S.D. Fla. 1992).[30] This duty (premised on the "inherent dangers" of a device) imposes a different standard than federal law, which requires "any relevant" warnings. Furthermore, the Florida duty could *require* warnings that the federal requirement *omits* because practitioners are commonly aware of the risks the warnings describe. 21 C.F.R. 801.109. As a result, the Florida duty is "different from, or in addition to," federal requirements.[31]

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threatens the health of patients, who may be frightened into abandoning use of a life-sustaining device or suffer psychological trauma from a notification.

[30] Plaintiffs assert failure-to-warn theories under both their negligence and strict liability causes of action. Although Florida law recognizes claims for failure to warn under both negligence and strict liability doctrines, the Florida courts have not drawn clear distinctions between the substantive duties imposed by the two types of claims. See, e.g., *Prather* v. *Upjohn Co.*, 797 F.2d 923, 926 (11th Cir. 1986); *Baione* v. *Owens-Illinois, Inc.*, 599 So. 2d 1377, 1378-79 (Fla. Dist. Ct. App. 1992). For purposes of preemption analysis, therefore, plaintiffs' negligence and strict liability failure-to-warn claims should be treated as one.

[31] Three courts of appeals in addition to the court below have cited the prescription device labeling regulation as a basis for FDCA preemption of state common law claims alleging failure to warn. See Pet. App. 33a; *Mendes* v. *Medtronic, Inc.*, 18 F.3d at 18; *Duvall* v. *Bristol-Myers-Squibb Co.*, 65

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Second, the failure-to-warn claims are preempted by the general misbranding requirements of the FDCA barring inadequate warnings. The Solicitor General argues that the generality of the misbranding provisions makes it very difficult to determine whether they impose standards different from plaintiffs' claims. See U.S. Br. 28.[32] That argument is illogical. Plaintiffs' complaint does not assert that Medtronic has violated the federal misbranding provisions, yet it does claim that the common law duty to warn has been breached. R1-3. Plaintiffs' claims therefore rest on the premise that compliance with the federal standard is insufficient, and that Florida tort law required additional and different warnings. By challenging the sufficiency of the federal standard, the state tort duty is *by definition* different, and the claims are preempted. Cf. *McDermott* v. *Wisconsin*, 228 U.S. 115, 132 (1913) (general misbranding provision in FDCA predecessor statute impliedly preempted state food labeling requirement).

Finally, plaintiffs' claims are preempted by the 510(k) requirements. By reviewing labeling submitted in the 510(k) application and clearing the device for marketing, the FDA made the decision that the Model 4011 can be marketed with the labeling submitted, and that Medtronic cannot change the labeling in a manner that could significantly affect safety or effectiveness without further FDA review and clearance. See, e.g., *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d at 399-400 ("[F]or all intents and purposes, [manufacturer] is required to continue to * * * label the device as proposed in its original 510(k) Notification."). Furthermore, the FDA has not exercised its

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F.3d 392, 399 (4th Cir. 1995), petition for cert. pending, No. 95-1010; *Feldt* v. *Mentor Corp.*, 61 F.3d at 436.

[32] One of the misbranding requirements the Solicitor General cites (relating to adequate directions for use) does not apply to the Model 4011 because it is a prescription device. See U.S. Br. 27; 21 C.F.R. 801.109 (exempting prescription devices from requirement to provide adequate directions for use).

authority to require additional warnings after it cleared the Model 4011 for marketing. See 21 U.S.C. 360h(a), (e); 21 C.F.R. 895.25. In contrast, plaintiffs claim that the labeling cleared by the FDA is inadequate, and that Florida common law required Medtronic to give different, and additional, warnings. Section 360k(a) preempts such claims.[33]

III. THE FDCA PREEMPTS PLAINTIFFS' DEFECTIVE MANUFACTURING CLAIMS

In discussing the defective manufacturing claims—as in discussing the labeling claims—plaintiffs, their amici, and the Solicitor General ask the wrong question and, predictably, get the wrong answer. *Numerous* federal requirements govern manufacturing, and plaintiffs' claims would impose different and additional requirements under state law. They are therefore preempted.

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[33] Because the state duty would require Medtronic to change its warnings and the federal requirements bar such changes without FDA clearance, the failure-to-warn claims would establish requirements in direct conflict with federal law. Like the design claims discussed in Medtronic's opening brief, see Pet. Br. 45 n.24, the failure-to-warn claims would be impliedly preempted even if this Court were to conclude that they are not expressly preempted. See, e.g., *English* v. *General Elec. Co.*, 496 U.S. 72, 79 (1990) (state law is impliedly preempted if "it is impossible for a private party to comply with both state and federal requirements"); *Freightliner Corp.* v. *Myrick*, 115 S. Ct. 1483, 1488 (1995) (existence of an express preemption provision does not foreclose implied preemption arising from actual conflict between federal and state law). Plaintiffs concede that implied preemption doctrine could invalidate their claims under some circumstances. Cross-Pet. Br. 23 n.6. And this Court recently has clarified that implied preemption doctrine applies in significantly broader circumstances than plaintiffs acknowledge. There is implied preemption not only when a federal statute *commands* actions that a state forbids, but also when "the Federal Statute authorizes * * * activities that the State * * * forbids." *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996), slip op. 5.

A. The FDCA Establishes Substantial Manufacturing Requirements for the Model 4011

1. The GMP Regulations Impose Significant Manufacturing Requirements

The GMP regulations impose significant controls on device manufacture, contrary to plaintiffs' suggestion that they are trivial requirements, "little more than common-sense standards for the production of any product." Cross-Pet. Br. 44.

The FDCA authorizes the FDA to prescribe regulations "requiring that the methods used in, and the facilities and controls used for," the manufacture of a device "conform to current good manufacturing practice * * * to assure that the device will be safe and effective and otherwise in compliance with [the Act]." 21 U.S.C. 360j(f)(1)(A). Although the FDA is ultimately responsible for promulgating these GMP regulations, the statute establishes an expert advisory committee to formulate them. *Id.* § 360j(f)(1)(B). The statute requires that the advisory committee be composed of nine members chosen from local, state, or federal government, the device industry, the health professions, and the general public. *Id.* § 360j(f)(3).[34] These varying interests effectuate the congressional intent by formulating requirements strict enough to ensure safety and effectiveness, but not so strict that they would be "likely to retard innovation, reduce efficiency, and hinder cost control." Device Good Manufacturing Practices Manual, HHS Pub. No. FDA 87-4179 (Nov. 1987) at iv.

The GMP requirements that emerge from this regulatory structure establish critical quality assurance standards for the

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[34] The statute also ensures broad public participation in the formulation of manufacturing requirements by mandating that the FDA must afford an opportunity for an oral hearing before the agency may promulgate proposed GMP regulations. *Id.* § 360j(f)(1)(B)(ii); 21 C.F.R. 15.1(b). After the regulations are proposed, the public has additional opportunities to participate through notice and comment rulemaking procedures.

medical device industry. These regulations require implementation of a quality assurance program covering all aspects of product manufacture. 21 C.F.R. 820.5. The GMP regulations establish requirements governing training, environmental control, and sanitation (*id.* §§ 820.25, .46, .56); equipment (*id.* §§ 820.60, .61); control of components (*id.* §§ 820.80, .81); production and process controls (*id.* §§ 820.100, .101, .115, .116); packaging and labeling controls (*id.* §§ 820.120, .121, .130); and inspection of finished devices (*id.* §§ 820.160, .161). Documented investigations of device failures also are required under the GMP regulations. *Id.* § 820.162. In addition, record-keeping requirements established in the GMP regulations apply to manufacture of devices. *Id.* §§ 820.180, .181, .182, .184, .185, .195, .198.

There certainly would be no need for the elaborate advisory committee structure described above if the plaintiffs' minimalization of the GMP regulations (Cross-Pet. Br. 44) were correct. In fact, the complexities of the GMP regulations have required the agency to issue hundreds of pages of guidance documents to aid its own investigators and industry in applying the quality assurance standards involved. See, e.g., Device Good Manufacturing Practices Manual, *supra*; FDA Compliance Program Guidance Manual, Transmittal No. 95-30 (Mar. 4, 1995). Furthermore, policing the GMP regulations has become a major thrust of the FDA's compliance program. Frequently, the majority of agency "warning letters" threatening enforcement actions derive from GMP issues, see, e.g., FDA Enforcement Manual Monthly Bulletin at 6 (Nov. 1994), and the FDA often initiates litigation to enforce the regulations, see, e.g., *United States* v. *Undetermined Quantities of Various Articles*, 800 F. Supp. 499 (S.D. Tex. 1992). As the court below properly explained, the agency's enforcement activity "foreclose[s] any suggestion that the GMP regulations are hortatory and without substantive effect." Pet. App. 31a.

2. The 510(k) Process Imposes Significant Manufacturing Requirements

Although the FDA's regulations do not explicitly require submission of manufacturing information in an original 510(k) application, the manufacturing process for a marketed device may not be changed in a manner that could significantly affect safety or effectiveness without 510(k) clearance. 21 C.F.R. 807.81(a)(3)(i).

The FDA has recognized that the 510(k) substantial equivalence requirements are inextricably linked to the GMP requirements in assuring reasonable safety and effectiveness of devices such as the Model 4011. Because the processes under which a device is manufactured fundamentally affect its safety and effectiveness, "both a change in manufacturing processes and a violation of [the GMP regulations] may have a significant impact on the question of substantial equivalence." 58 Fed. Reg. 57,614 (Oct. 26, 1993). As a result, the agency has concluded that a device that is manufactured under processes that constitute significant GMP violations "does not satisfy the criteria for a finding of substantial equivalence" under the FDCA. *Ibid.* The agency therefore enforces both 510(k) and GMP requirements to control device manufacturing.

B. The Federal Manufacturing Requirements Have Preemptive Effect Because They are "Applicable to the Device"

As the discussion at pages 25-27 *supra* explains, any FDCA requirement is preemptive as long as it is "applicable to the device." The 510(k) and GMP requirements described above easily fit within this phrase. In addition, Medtronic's opening brief and the discussion at page 25 *supra* also explain that two other sections of the FDCA refer to the 510(k) requirements as applicable to the device. See Pet. Br. 31-32. One of the same two sections also refers to the GMP requirements established under FDCA § 520(f) (21 U.S.C. 360j(f)) as "appl[icable] to the device," confirming their status as preemptive requirements. See

id. § 360c(d)(2)(A). See also U.S. Br. 24 n.19 (GMP regulations are "requirements" within the meaning of the FDCA preemption provision).

C. Plaintiffs' Defective Manufacturing Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011

Like the failure-to-warn claims discussed above, plaintiffs' defective manufacturing claims would establish state requirements "different from, or in addition to," applicable federal manufacturing requirements and meet all other criteria mandating preemption under the FDCA.

1. The GMP Requirements Preempt Plaintiffs' Defective Manufacturing Claims

Plaintiffs' defective manufacturing claims are preempted, because they would establish requirements "different from, or in addition to," the GMP regulations. Plaintiffs' complaint does not assert that Medtronic has violated the GMP regulations, but it does allege that the company violated the Florida negligence and strict liability standards. R1-3. The premise of plaintiffs' claims therefore is that a device manufactured in accordance with the GMP regulations is not sufficiently safe, and that Medtronic should have used a different manufacturing process. By asserting that Medtronic is exposed to state liability despite its compliance with the GMP regulations, plaintiffs' manufacturing claims necessarily would establish state requirements different from, and in addition to, those federal requirements.[35]

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[35] The court below and four other courts of appeals have held that the GMP regulations preempt defective manufacturing claims. See Pet. App. 31a; *Mendes* v. *Medtronic, Inc.*, 18 F.3d at 19; *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995); *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d at 399; *Feldt* v. *Mentor Corp.*, 61 F.3d at 436.

Nonetheless, the Solicitor General argues that there is no way to know whether plaintiffs' manufacturing claims would establish state requirements different from, or in addition to, the GMP requirements, because the federal requirements are phrased in general language that may *overlap* with state tort duties. U.S. Br. 22-25. Although the state and federal requirements may overlap to some extent, there also are areas in which they diverge, such as in the present case, in which plaintiffs allege that Medtronic should pay common law damages despite its compliance with the GMP regulations. As long as the state and federal requirements contain *some* differences, they are "different from" each other, even if they contain some similarities as well. See also Point IV, *infra*.

Furthermore, a comparison of the state and federal requirements at issue confirms their differences. First, plaintiffs' strict liability manufacturing claim would establish a state-law requirement different from the GMP requirements. Under Florida law, a manufacturer is subject to strict liability for distributing a product in a defective condition unreasonably dangerous to foreseeable users and bystanders. *Witt* v. *Norfe, Inc.*, 725 F.2d 1277, 1278 (11th Cir. 1984). In contrast, a manufacturer is liable for producing devices in violation of the GMP regulations even if those devices have no defects and are not at all dangerous to the user. See, e.g., *United States* v. *789 Cases*, 799 F. Supp. 1275, 1286 (D.P.R. 1992) (the FDA need not prove that the devices have defects or cause harm to prove GMP violations). The reason defects and dangers need not be shown is that the GMP regulations have a preventive purpose and are intended to "build in" quality prospectively to minimize the possibility of a defective device. Cf. 43 Fed. Reg. at 31,509 (July 21, 1978) (preamble to GMP regulations).

Second, plaintiffs' negligent manufacturing claim would establish state-law requirements different from the GMP requirements. The state-law duty underlying plaintiffs' negligence claim is a standard of reasonable care in product manufacture, imposed so that products will be reasonably safe for use in a

foreseeable manner. See, e.g., *Witt* v. *Norfe, Inc.*, 725 F.2d at 1278. In contrast, the GMP requirements derive not from what is "reasonable" but instead from "basic principles of quality assurance" that "have as their goal the production of articles that are fit for their intended uses." 43 Fed. Reg. at 31,509. The FDA explains those principles as follows (*ibid.*):

> (1) Quality, safety, and effectiveness must be designed and built into the product; (2) quality cannot be inspected or tested into the finished product; (3) each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications.

At the time the agency first promulgated the GMP regulations, device manufacturers had not yet adopted adequate quality assurance programs. Some firms had no programs at all, and the FDA estimated that the firms that did have programs were complying only with about half of the quality assurance requirements established through the GMP regulations. *Ibid.* As a result, the GMP regulations imposed new and different requirements on manufacturers that had been governed by common law duties before enactment of the MDA. There is no basis whatsoever for suggesting that the GMPs and the common law (which governed device manufacturers before 1976) are identical.

Finally, preemption of plaintiffs' manufacturing claims under the GMP requirements is consistent with the federal statutory structure. The FDCA assigns an expert advisory committee the responsibility for formulating manufacturing requirements. See pp. 32-33, *supra*. In contrast, plaintiffs' common law claims would allow a state judge and jury to determine the methods by which the Model 4011 lead should be manufactured. Preemption of those claims reserves implementation of manufacturing requirements to the federal government in accordance with the statutory procedures, as Congress intended.

2. The 510(k) Requirements Preempt Plaintiffs' Defective Manufacturing Claims

Plaintiffs' claims based on alleged manufacturing defects also are preempted because of the 510(k) requirements described above. Plaintiffs assert that Medtronic's manufacturing process was inadequate, and that it should have used a different process to produce a safer device. On the other hand, the FDCA prohibits the manufacturer of a device cleared through the 510(k) process from changing its manufacturing process in a way that could affect safety or effectiveness significantly without obtaining additional 510(k) clearance. 21 C.F.R. 807.81(a)(3)(i). State requirements that would be imposed through plaintiffs' manufacturing claims therefore are preempted under section 360k(a), because they are different from, or in addition to, the federal regulation requiring FDA clearance for manufacturing changes.[36]

IV. EVEN IF BASED ON FEDERAL STANDARDS, PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD IMPOSE REQUIREMENTS THAT ARE "DIFFERENT FROM, OR IN ADDITION TO," APPLICABLE FEDERAL REQUIREMENTS

In holding that plaintiffs' failure-to-warn and defective manufacturing claims are preempted, the court of appeals stated that "preemption under the MDA cannot be defeated by a common-law suit alleging a violation of the [federal] statutory standards." Pet. App. 13a-14a. A contrary result would permit lay juries, rather than the expert federal agency, to determine such complex issues as whether a medical device's "labelling and packaging information is incomplete or inaccurate, and if so what label changes, if any, should be made." Pet. App. 13a

[36] This conflict between state and federal law also invalidates plaintiffs' defective manufacturing claims under the implied preemption doctrine. See p. 31 n. 33 *supra*.

(quoting *Papas* v. *Upjohn Co.*, 985 F.2d 516, 519 (11th Cir.), cert. denied, 114 S. Ct. 300 (1993)). The Eleventh Circuit's conclusion followed "[e]very circuit court decision addressing this issue under the MDA." Pet. App. 14a.

Plaintiffs' complaint does not assert a claim for violation of federal requirements R 1-3.[37] Nonetheless, plaintiffs contend that their tort claims would be preserved if they were recast as claims that "seek only to enforce federal standards" (Cross-Pet. Br. 45-46), because they would not then impose any requirements that are "different from, or in addition to," the federal requirements applicable to the Model 4011. The United States agrees that identical state requirements are not "different from, or in addition to," the federal requirements, and further maintains that damages remedies based on such identical standards are not "requirements" at all. U.S. Br. 11-15, 22-28.[38]

[37] Florida law may not even recognize such a claim. For example, under Florida law, it may well be inappropriate to instruct the jury that the doctrine of negligence per se applies, even if an alleged statutory violation typically constitutes negligence. *Underwriters at LaConcorde* v. *Airtech Servs., Inc.*, 493 So. 2d 428, 431 (Fla. 1986) (Boyd, J., concurring in part and dissenting in part). Furthermore, the Florida courts have not resolved definitively whether negligence per se even applies to violations of administrative regulations as well as to violations of statutes. *Id.* at 430. It is even less clear whether negligence per se applies to violations of federal regulations. See, e.g., *Murray* v. *Briggs*, 569 So. 2d 476, 480 (Fla. Dist. Ct. App. 1990) ("[A]lthough several courts seem comfortable with the concept, we are not satisfied that a federal regulation should necessarily control state-law questions of negligence by enlarging common law duties or creating new duties.") (footnote omitted), review denied, 581 So. 2d 165 (Fla. 1991); see also *Cadillac Fairview of Fla., Inc.* v. *Cespedes*, 468 So. 2d 417, 421 (Fla. Dist. Ct. App.) (OSHA violation not dispositive on state-law questions of negligence or products liability), review denied, 479 So. 2d 117 (Fla. 1985).

[38] As the United States notes, an FDA regulation has interpreted the statutory phrase "different from, or in addition to," as excluding state requirements that are "equal to" or "substantially identical" to the applicable federal requirements. U.S. Br. 12-13 (quoting 42 Fed. Reg. at 30,384); accord 21 C.F.R. 808.1(d)(2). The government, however, notably refrains from asking this Court to defer to that agency pronouncement. A state requirement

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In pressing the latter argument, the government purports to rely on the FDA's "consistent[], and reasonabl[e], construc[tion of] the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10.

The Court should reject all of these arguments. Plaintiffs' interpretation is contrary to the language and structure of the preemption clause. Their interpretation also is wrong, because it would undermine the congressional intent to establish uniform device requirements. In addition, the government is mistaken in arguing that tort-law damages remedies do not qualify as "requirements." In fact, the FDA on several occasions has indicated that state enforcement provisions and remedies *are* "requirements." Accordingly, plaintiffs' damages claims are preempted even if they were recast as based on federal standards.

A. State Requirements Are "In Addition To" Federal Requirements Even When They Embody Identical Standards

Plaintiffs and the government do not make *any* effort to explain how the phrase "different from, or in addition to," can be read to exclude state requirements that are identical to federal requirements. This is not surprising, because the statutory language is not susceptible to the interpretation they advocate—for at least four reasons.

1. Plaintiffs' interpretation treats the statute as if it refers only to state requirements that are "different" and thus fails to give *any* independent meaning to the phrase "in addition to." But Congress did not limit preemption to state requirements that are "different from" federal requirements; it said that requirements that are either "different from, *or in addition to*," federal requirements are preempted. Each word of a statute must

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that is only "substantially identical" to a federal requirement would be—almost by definition—"different from" the federal requirement and therefore plainly preempted.

be afforded some meaning. See, e.g., *United States Department of Treasury* v. *Fabe*, 113 S. Ct. 2202, 2210 n.6 (1993). That basic tenet of statutory construction alone defeats plaintiffs' argument.

As a matter of ordinary usage, a state requirement that is identical in content to a federal requirement could fairly be described as an "addition[al]" requirement (just as a second coat of paint of the same color "adds to" or is "in addition to" the first coat). Indeed, this is the *most natural* reading of the phrase "in addition to." State requirements "add to" federal requirements by imposing another set of substantive rules, even if the content of both sets of rules is the same. The manufacturer's obligation to comply with an identical state requirement is completely independent of any federal-law compliance requirement. And again, the phrase "in addition to" must include *some* requirements that are identical, because that is all that remains after "different" state requirements are preempted. Thus, the language of Section 360k(a) does not preserve state requirements that are identical to federal requirements.

Furthermore, plaintiffs allege that Florida law imposes on Medtronic the *requirement* to pay compensatory damages for a violation of standards identical to the federal standards—a requirement that federal law does not impose.[39] Thus, the phrase "in addition to" encompasses that requirement as well as any state requirement that is identical to the federal requirements.

2. Congress knows how to write a preemption provision preserving identical state requirements, as it did in two other sections of the FDCA. See 21 U.S.C. 343-1(a) (preempting state

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[39] Under the FDCA, the federal government's potential remedies include seizures, injunctions, civil penalties, criminal penalties, cease and desist orders, and orders requiring recalls, notification of hazards and device repairs, replacements, or refunds. 21 U.S.C. 331-334, 360h. Plaintiffs' demand for payment of damages under state law is a substantial additional requirement different from, and in addition to, these FDCA remedies.

food requirements "not identical to" federal requirements); *id.* § 360ss (preempting state radiation standards "not identical to" federal standards). Similarly, Congress has stated explicitly in other statutes' preemption provisions that identical state requirements are not preempted. See, e.g., 15 U.S.C. 1476(a), 2075(a), 2617(a)(2)(B); 49 U.S.C. 30103(b); 46 U.S.C. 4306. See generally MDMA Br. 19 n.25 (quoting similar statutes). Yet Congress obviously did not use such language in drafting the broader preemption provision of the MDA.

In fact, during its consideration of the MDA, Congress *rejected* two versions of the preemption provision that would have exempted identical state requirements. Both an early House bill and the Senate bill that was sent to conference (where its version of the preemption provision was rejected) provided that state requirements were preempted unless they were "identical to" certain federal requirements. H.R. 9984, 93d Cong., 1st Sess. (1973); 121 Cong. Rec. S 6161 (daily ed. Apr. 17, 1975). Congress, however, significantly broadened this language in the final bill to encompass state requirements that are "different from, or in addition to," federal requirements. If Congress had meant to say that it preserved state law "identical to" federal law, it easily could have—and would have—done so.

3. Other preemption provisions in the U.S. Code confirm that, when Congress directs the preemption of state requirements that are "in addition to" or "different from" federal requirements, it does not intend to spare "identical" state requirements. Indeed, the phrase sweeps so broadly that is has been used to mandate preemption of an entire field of state regulation. See 7 U.S.C. 4817 (in statute "intended to occupy the field of—(1) promotion and consumer education involving pork and pork products; and (2) obtaining funds therefor from pork producers," stating that, during certain periods and with certain exceptions, "[t]he regulation of such activity * * * that is *in addition to or different from* this chapter may not be imposed by a State") (emphasis added); see also *Lynbrook Farms* v. *Smithkline Beecham Corp.*, No. 95-2051, slip op. 2, 6-7, 17 (7th

Cir. Mar. 21, 1996) (affirming field preemption under agency regulation prohibiting state "requirements . . . different from, or in addition to, those imposed by USDA" even though "the conclusion we reach today leaves Lynbrook and similar plaintiffs no remedy for the injuries and losses they have suffered"). In addition, other statutes preempt "additional" or "different" state requirements but provide an explicit *exception* preserving state requirements that are consistent with federal law. See, e.g., 21 U.S.C. 678; *id.* § 1052(a), (b). Congress, of course, made no such exception in the FDCA preemption provision.

4. As plaintiffs acknowledge, there is no express or implied private right of action for violation of the FDCA or related regulations. Cross-Pet. Br. 30-31 (citing *Bailey* v. *Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995)); see also 21 U.S.C. 337 ("[P]roceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Congress's omission of a private right of action reflects an intent to reserve enforcement of federal requirements exclusively to the federal government. It is most unlikely that Congress intended to foreclose private enforcement of federal norms but to allow states to permit such private enforcement of identical norms under state law. See MDMA Br. 23-26. For that reason as well, the Court should reject plaintiffs' interpretation.[40]

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[40] Cf. *Merrell Dow Pharmaceuticals Inc.* v. *Thompson*, 478 U.S. 804, 812 n.10 (1986) ("When we conclude that Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless.' "); *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.) (claim for FDCA violation barred because no private right of action exists), cert. denied, 115 S. Ct. 429 (1994).

B. Plaintiffs' Construction of the Statute is Inconsistent With the Congressional Intent to Establish Uniform Requirements

Although plaintiffs theorize that it would be possible to cast common law claims so that they necessarily would establish requirements identical to federal standards, their theory departs from reality. The inability of courts to ensure consistency in practice would create an irregular pattern of liability exposure for device manufacturers, undermining the congressional intent to impose uniform requirements. The danger that such a regime would frustrate the fundamental objective of the preemption provision reinforces the conclusion that, if Congress had intended to preserve "identical" state requirements from preemption, it would have said so in the text of the statute.

If the FDCA preserved claims for violation of state standards that are identical to federal requirements, differing *interpretations* of federal requirements inevitably would arise as these claims were adjudicated. There is no reason to expect that a lay jury or state judge interpreting a federal requirement necessarily would reach the same construction as the FDA, particularly in cases such as this one, in which there has been no suggestion that the agency believes its requirements have been violated. The risk that state juries and judges would interpret identical requirements inconsistently or "different[ly]" from the FDA is greatly heightened, moreover, because many federal requirements are cast in relatively broad terms.[41]

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[41] As administered by the FDA, the federal enforcement scheme established by the statute substantially ensures that the federal government will take uniform positions in litigation involving interpretations of the FDCA and related regulations. The FDA General Counsel's Office must approve all enforcement actions for legal sufficiency (Arthur N. Levine, FDA Enforcement Manual at 71 (Apr. 1994)), and those actions filed in federal court also are coordinated through the Civil Division of the Department of

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These varying interpretations would render the state requirements "different" from the federal requirements, and therefore preempted. This Court has made clear that preemption depends upon "the relationship between state and federal laws as they are interpreted and applied, not merely as they are written." *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 526 (1977). The FDA also has acknowledged that a state's *application* of a requirement determines whether it is different from, or in addition to, the federal requirement under the FDCA preemption provision. See, e.g., 43 Fed. Reg. 18,661, 18,663 (May 2, 1978); 21 C.F.R. 808.20(c)(1) (requiring submission of judicial and administrative interpretations in petition for exemption from preemption). As a result, claims premised upon these differing interpretations could not survive preemption. Cf. *Merrell Dow*, 478 U.S. at 815 ("[t]o the extent that petitioner is arguing that state use and interpretation of the FDCA pose a threat to the order and stability of the FDCA regime, petitioner should be arguing * * * that the FDCA pre-empts state-court jurisdiction" over state common law claims for FDCA violations). The irrational pattern of liability exposure that would emerge from varying case-by-case interpretations of the federal requirements is so inconsistent with the expressed congressional desire to promote uniformity that it is reasonable

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Justice. See 28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(9), (10). This coordination helps assure that judicial interpretations of the FDCA and related regulations are uniform. In contrast, permitting private plaintiffs to adopt and assert their own interpretations of the federal requirements in product liability litigation without any nationwide coordination by, or oversight from, the federal experts would inevitably lead to imposition of differing standards. Indeed, as the United States acknowledges, private plaintiffs could assert that a manufacturer has violated FDCA requirements *even if the FDA disagrees*. U.S. Br. 26.

to conclude that if Congress had intended to preserve "identical" state requirements, it would have said so explicitly.[42]

Furthermore, the extraordinary practical difficulties of such a regime confirm that plaintiffs' construction of the statute is wrong. If a state jury determined that a device's labeling was "false and misleading" under the "federal" standard because it omitted some information, a manufacturer would be obliged to change the labeling at least in that state or else risk additional adverse verdicts (possibly even punitive damages awards). But to effectuate such a change the manufacturer would need clearance from the FDA. The FDA, however, might withhold clearance on the ground that the existing labeling is *not* false and misleading, or because the new information would dilute other warnings that the agency deems more important. Worse yet, it is conceivable that *many* states, acting through common law tort actions purportedly applying general federal requirements to specific devices as part of the "identical" law of each state, would impose *irreconcilable* requirements on a manufacturer. And there is no guarantee that the FDA would decide which conflicting interpretation of federal standards is correct. This pattern of conflicting standards would be wholly inconsistent with the congressional intent to promote uniformity.

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[42] The Solicitor General suggests that state juries could simply be instructed to determine whether a device's labeling is "false and misleading" or bears "adequate directions for use." U.S. Br. 27. Making a virtue of necessity, the Solicitor General points out that he "cannot say" that a jury's determination of such issues "would of necessity rest on any common-law duty of care that is 'different from, or in addition to,' (21 U.S.C. 360k(a)(1)) the Act's labeling provisions." U.S. Br. 28. That is precisely our point. Under the regime advocated by the government, preemption could be determined, if at all, only after the jury's verdict in a post-trial motion—an odd result indeed (as well as a colossal waste of judicial resouces).

C. The Obligation To Pay Damages Is A "Requirement"

Evidently recognizing that plaintiffs' claims, if successful, would require Medtronic to do something "different from, or in addition to," what federal law requires, the Solicitor General contends that an obligation to pay damages rooted in state tort law is not a "requirement" within the meaning of Section 360k(a). He further suggests the FDA has "consistently, and reasonably, construed the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10. Those assertions are wrong.

1. There is no basis *in the text of the statute* for distinguishing between an obligation to conform a medical device's design, labeling, or manufacture to state-law standards and an obligation to pay damages for the violation of such a standard. Both are "requirements." Indeed, two sections of the FDCA refer to 21 U.S.C. 360h—which is entitled "Notification And Other Remedies" and is devoted exclusively to remedies—as prescribing "requirement[s]." 21 U.S.C. 352(t), 331(q)(1). As the Solicitor General elsewhere concedes (U.S. Br. 24 n.19), something that is described as a "requirement" elsewhere in the FDCA should be regarded as a "requirement" for purposes of the preemption provision. It follows that remedies *are* "requirements."

The distinction drawn by the government is particularly untenable in light of the authority of state attorneys general to obtain equitable remedies for violations of common law duties. See, e.g., *Mayor of Georgetown* v. *Alexandria Canal Co.*, 37 U.S. (12 Pet.) 91, 98 (1838); *State* v. *First Nat'l Bank*, 600 P.2d 406, 421 (Alaska 1982). Under the government's reading, a state could enjoin distribution of a device under its common law for violating a federal requirement, even though the FDA had decided both that the same violation is trivial *and* that continued distribution of the device is in the public interest. See 21 U.S.C. 336 ("Nothing in [the FDCA] shall be construed as requiring the

Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of [the FDCA] whenever he believes that the public interest will be adequately served by a suitable written notice or warning."). There is no reason to attribute to Congress a design that would produce such an absurd result.

2. The United States can draw no support from previous statements of the FDA relating to Section 360k(a). Contrary to the Solicitor General's submission, the FDA has *not* previously "construed the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10. That novel interpretation is nothing more than an invention of the government's litigators in this case. Indeed, several of the agency pronouncements cited by the government conclusively establish that the agency has recognized that state "remedies" *are* a kind of "requirement" within the meaning of Section 360k(a).

The Solicitor General points to three FDA statements. U.S. Br. 12-13. First, he notes that the FDA has interpreted Section 360k(a) not to preempt *identical* or *substantially identical* state requirements. U.S. Br. 12. That is true but irrelevant, because this interpretation rests not on the word "requirement" but rather on the phrase "different from, or in addition to." 43 Fed. Reg. at 18,663; 42 Fed. Reg. 30,383, 303,84 (June 14, 1977).

Second, the Solicitor General notes that the FDA has said that Section 360k(a)

> does not preempt those State or local *requirements respecting general enforcement*, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments.

21 C.F.R. 808.1(d)(6)(i) (emphasis added), cited in U.S. Br. 13. According to the Solicitor General, this passage demonstrates that the FDA has long recognized the distinction between remedies and substantive requirements. That is doubly incorrect.

The quoted passage, by referring to state enforcement provisions as "requirements," flatly *refutes* the government's assertion (and shows that the FDA *does* regard enforcement provisions as "requirements"). In addition, the FDA's *reason* for concluding that state enforcement provisions are preserved was its former view—which rested on language in the preemption clause *other than* the word "requirement"—that state requirements of "general applicability" are not preempted (a view that the United States elsewhere rejects in its brief). See 42 Fed. Reg. at 30,384; 43 Fed. Reg. at 18,663.

For exactly the same reasons, the 1984 FDA advisory opinion cited by the government (U.S. Br. 13; see Cross-Pet. Br. 12a-13a) actually refutes the agency interpretation claimed in the government's brief. According to the Solicitor General, that FDA letter "made clear that the state 'enforcement provisions' that [the FDA] considers not to constitute 'requirement[s]' include *judicial* remedies sought by private parties to enforce state substantive requirements." U.S. Br. 13. In fact, the letter asserts that remedies *are* requirements, stating that Congress did not intend preemption of "State or local *requirements* respecting general enforcement, *including available legal remedies*, or State or local statutes that only incidentally apply to devices." Cross-Pet. Br. 13a (emphasis added). The agency's reason for reaching this conclusion was its former (and now repudiated) view that requirements of general applicability are not preempted. *Ibid.*

In short, far from "consistently, and reasonably, construe[ing] the term 'requirement' to refer to substantive, but not remedial, provisions" (U.S. Br. 9-10), the FDA has on several occasions indicated that "requirements" include state remedies and enforcement provisions. This Court also should conclude that remedies are state requirements subject to FDCA preemption.

CONCLUSION

The Court should affirm in part the judgment of the Eleventh Circuit and hold that the Federal Food, Drug, and Cosmetic Act preempts plaintiffs' negligence and strict liability claims for failure to warn and defective manufacture regarding the Medtronic Model 4011 cardiac pacemaker lead.

Respectfully submitted,

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims alleging defective manufacturing and labeling of a medical device that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

TABLE OF CONTENTS

QUESTION PRESENTED i
TABLE OF AUTHORITIES v
SUMMARY OF ARGUMENT 6
ARGUMENT 8
I. COMMON LAW CLAIMS ESTABLISH STATE REQUIREMENTS SUBJECT TO PREEMPTION UNDER THE FDCA 9
A. This Court Should Reject Plaintiffs' Re-Argument of Issues Resolved in *Cipollone* 9
B. The Language of the FDCA Preemption Provision Encompasses Common Law Claims 12
1. The Preemption Provision's Use of the Term "Requirement" Three Times Does Not Exclude State Common Law Claims 12
2. The FDCA Does Not Restrict Preemption to State Requirements That Apply Exclusively to Devices 13
C. Other Provisions of the FDCA Support Preemption of Common Law Claims 16
II. THE FDCA PREEMPTS PLAINTIFFS' FAILURE-TO-WARN CLAIMS 18
A. The FDCA Establishes Substantial Requirements for Product Warnings Concerning the Model 4011 21
1. The 510(k) Process Imposes Substantial Requirements Concerning Labeling Warnings 21
2. The Prescription Device Labeling Regulation Imposes Substantial Warning Requirements 22

3. The FDCA and Related Regulations Give the FDA Substantial Authority to Require Additional Warnings After Marketing Begins and Prohibit Distribution of Devices with Inadequate Warnings 24
B. The Federal Warning Requirements Have Preemptive Effect Because They Are "Applicable to the Device" 25
C. Plaintiffs' Failure-to-Warn Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011 27
III. THE FDCA PREEMPTS PLAINTIFFS' DEFECTIVE MANUFACTURING CLAIMS 31
A. The FDCA Establishes Substantial Manufacturing Requirements for the Model 4011 32
1. The GMP Regulations Impose Significant Manufacturing Requirements 32
2. The 510(k) Process Imposes Significant Manufacturing Requirements 34
B. The Federal Manufacturing Requirements Have Preemptive Effect Because They are "Applicable to the Device" 34
C. Plaintiffs' Defective Manufacturing Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011 35
1. The GMP Requirements Preempt Plaintiffs' Defective Manufacturing Claims 35

2. The 510(k) Requirements Preempt Plaintiffs' Defective Manufacturing Claims.....38

IV. EVEN IF BASED ON FEDERAL STANDARDS, PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD IMPOSE REQUIREMENTS THAT ARE "DIFFERENT FROM, OR IN ADDITION TO," APPLICABLE FEDERAL REQUIREMENTS.....38

A. State Requirements Are "In Addition To" Federal Requirements Even When They Embody Identical Standards.....40

B. Plaintiffs' Construction of the Statute is Inconsistent With the Congressional Intent to Establish Uniform Requirements.....44

C. The Obligation To Pay Damages Is A "Requirement".....47

CONCLUSION.....50

TABLE OF AUTHORITIES

CASES Page

American Airlines, Inc. v. *Wolens*, 115 S. Ct. 817 (1995).....15,18

Arkansas Louisiana Gas Co. v. *Hall*, 453 U.S. 571 (1981).....5

Baione v. *Owens-Illinois, Inc.*, 599 So. 2d 1377 (Fla. Dist. Ct. App. 1992).....29

Barnett Bank v. *Nelson*, No. 94-1837 (Mar. 26, 1996).....14,20,31

Bourjaily v. *United States*, 483 U.S. 171 (1987).....2

Brown v. *Gardner*, 115 S. Ct. 552 (1994).....11

Cadillac Fairview of Florida, Inc. v. *Cespedes*, 468 So. 2d 417 (Fla. Dist. Ct. App.), review denied mem., 479 So. 2d 117 (Fla. 1985).....39

Central Bank of Denver, N.A. v. *First Interstate Bank of Denver, N.A.*, 114 S. Ct. 1439 (1994).....11

Chevron, U.S.A., Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).....15

Chicago & Northwestern Transportation Co. v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981).....10

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992).....4,6,9,10,11,12,15

Coastal Petroleum Co. v. *American Cyanamid Co.*, 492 So. 2d 339 (Fla. 1986), cert. denied, 479 U.S. 1065 (1987).....13

CSX Transportation, Inc. v. *Easterwood*, 507 U.S. 658 (1993).....4,6,10,11

TABLE OF AUTHORITIES continued

Page

Duvall v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), petition for cert. pending, No. 95-1010 29,30,35

Eli Lilly & Co. v. *Medtronic, Inc.*, 496 U.S. 661 (1990) 12

English v. *General Electric Co.*, 496 U.S. 72 (1990) 4,30

Feldt v. *Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), petitions for cert. pending, Nos. 95-1037, 95-1214 26,29,30,35

Freightliner Corp. v. *Myrick*, 115 S. Ct. 1483 (1995) 30

Garcia v. *United States*, 469 U.S. 70 (1984) 2

Gile v. *Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994) 43

Gillespie v. *United States Steel Corp.*, 379 U.S. 148 (1964) 5

International Paper Co. v. *Ouellette*, 479 U.S. 481 (1987) 10

Jones v. *Rath Packing Co.*, 430 U.S. 519 (1977) 45

Kennedy v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) 8

Kordel v. *United States*, 335 U.S. 345 (1948) 21

Lynnbrook Farms v. *Smithkline Beecham Corp.*, No. 92-2051 (7th Cir. Mar. 21, 1996) 42

Mayor of Georgetown v. *Alexandria Canal Co.*, 37 U.S. (12 Pet.) 91 (1838) 47

McDermott v. *Wisconsin*, 228 U.S. 115 (1913) 30

TABLE OF AUTHORITIES continued

Page

Mendes v. *Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) 28,29,35

Merrell Dow Pharmaceuticals Inc. v. *Thompson*, 478 U.S. 804 (1986) 43,45

Michael v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995) 35

Moore v. *Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) 25

Morales v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) 11,15,18

Murray v. *Briggs*, 569 So. 2d 476 (Fla. Dist. Ct. App. 1990), review denied mem., 581 So. 2d 165 (Fla. 1991) 39

Patterson v. *McLean Credit Union*, 491 U.S. 164 (1989) 11

Pension Benefit Guaranty Corp. v. *LTV Corp.*, 496 U.S. 633 (1990) 11

Pilot Life Insurance Co. v. *Dedeaux*, 481 U.S. 41 (1987) 5

Prather v. *Upjohn Co.*, 797 F.2d 923 (11th Cir. 1986) 29

Rodriguez v. *United States*, 480 U.S. 522 (1987) (per curiam) 2

San Diego Building Trades Council v. *Garmon*, 359 U.S. 236 (1959) 5,10

Silkwood v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984) 4

TABLE OF AUTHORITIES continued

Page

Stanley Industries, Inc. v. *W.M. Barr & Co.*, 784 F. Supp. 1570 (S.D. Fla. 1992).....29

State v. *First National Bank*, 660 P.2d 406 (Alaska 1982).....47

Texas & Pacific Railway v. *Abilene Cotton Oil Co.*, 204 U.S. 426 (1907).....18

Underwriters at LaConcorde v. *Airtech Services*, 493 So. 2d 428 (Fla. 1986).....39

United Construction Workers v. *Laburnum Construction Corp.*, 347 U.S. 656 (1954).....4,5

United States Department of Treasury v. *Fabe*, 113 S. Ct. 2202 (1993).....41

United States v. *11,307 Boxes*, No. 93-574 (S.D. Fla. filed Mar. 26, 1993).....22

United States v. *789 Cases*, 799 F. Supp. 1275 (D.P.R. 1992).....36

United States v. *An Article of Device*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984).....23

United States v. *Articles of Device*, 426 F. Supp. 366 (W.D. Pa. 1977).....23

United States v. *James*, 478 U.S. 597 (1986).....2

United States v. Park, 421 U.S. 658 (1975).....37

United States v. *Undetermined Quantities of Various Articles*, 800 F. Supp. 499 (S.D. Tex. 1992).....33

Witt v. *Norfe, Inc.*, 725 F.2d 1277 (11th Cir. 1984).....36,37

TABLE OF AUTHORITIES continued

Page

Zanzuri v. *G.D. Searle & Co.*, 748 F. Supp. 1511 (S.D. Fla. 1990).....28

STATUTES

7 U.S.C. 4817.....42
15 U.S.C. 1476(a).....42
15 U.S.C. 2075(a).....42
15 U.S.C. 2617(a)(2)(B).....42
21 U.S.C. 321(k).....21
21 U.S.C. 321(m).....20
21 U.S.C. 331.....40
21 U.S.C. 331(q)(1).....47
21 U.S.C. 332.....40
21 U.S.C. 333.....40
21 U.S.C. 334.....24,40
21 U.S.C. 336.....47
21 U.S.C. 337.....43
21 U.S.C. 343-1(a)(1).....41
21 U.S.C. 352.....25
21 U.S.C. 352(a).....24
21 U.S.C. 352(f)(2).....24
21 U.S.C. 352(j).....24
21 U.S.C. 352(t).....47
21 U.S.C. 360c(d)(2)(A).....35
21 U.S.C. 360f.....24
21 U.S.C. 360h.....17,40,47
21 U.S.C. 360h(a).....24,31
21 U.S.C. 360h(a)(2).....28

TABLE OF AUTHORITIES continued

Page

21 U.S.C. 360h(b) 17
21 U.S.C. 360h(b)(3) 5
21 U.S.C. 360h(d) 7,17,18
21 U.S.C. 360h(e) 24,31
21 U.S.C. 360i 24
21 U.S.C. 360j(a) 25
21 U.S.C. 360j(f) 34
21 U.S.C. 360j(f)(1)(A) 32
21 U.S.C. 360j(f)(1)(B) 32
21 U.S.C. 360j(f)(1)(B)(ii) 32
21 U.S.C. 360j(f)(3) 32
21 U.S.C. 360k(a) ..... *passim*
21 U.S.C. 360k(a)(1) 12,20,25,46
21 U.S.C. 360k(a)(2) 2,12,20
21 U.S.C. 360k(b) 4,16
21 U.S.C. 360k(b)(1) 2
21 U.S.C. 360ss 43
21 U.S.C. 678 42
21 U.S.C. 1052(a) 42
21 U.S.C. 1052(b) 43
46 U.S.C. 4306 41
49 U.S.C. 30103(b) 41
Conn. Gen. Stat. Ann. §§ 52-572m to 52-572q (West 1991) 13
Ind. Code Ann. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996) 13
La. Rev. Stat. Ann. §§ 9:2800.51 to 9:2800.59 (West 1991) 13

TABLE OF AUTHORITIES continued

Page

Me. Rev. Stat. Ann. tit. 14, § 221 (West 1980) 13
Miss. Code Ann. § 11-1-63 (Supp. 1994) 13
Mont. Code Ann. § 27-1-719 (1993) 13
N.C. Gen. Stat. §§ 99B-1 to 99B-11 (Michie 1995) 13
Ohio Rev. Code Ann. §§ 2307.71 to 2307.80 (Baldwin 1996) 13
S.C. Code Ann. §§ 15-73-10 to 15-73-30 (Law. Co-op. 1993) 13

REGULATIONS

21 C.F.R. 10.25 5
21 C.F.R. 10.30 5
21 C.F.R. 15.1(b) 32
21 C.F.R. 801.109 22,23,25,28,29
21 C.F.R. 801.109(a)(2) 23
21 C.F.R. 801.109(b)(1) 23
21 C.F.R. 801.109(c) 23,29
21 C.F.R. 807.81(a)(3) 22
21 C.F.R. 807.81(a)(3)(i) 22,34,38
21 C.F.R. 807.87(e) 21
21 C.F.R. 807.87(k) 21
21 C.F.R. 808.1(d)(1) 14
21 C.F.R. 808.1(d)(2) 39
21 C.F.R. 808.1(d)(6)(i) 48
21 C.F.R. 808.20(c)(1) 45
21 C.F.R. 820.5 33
21 C.F.R. 820.25 33
21 C.F.R. 820.46 33

TABLE OF AUTHORITIES continued

Page

21 C.F.R. 820.56 33
21 C.F.R. 820.60 33
21 C.F.R. 820.61 33
21 C.F.R. 820.80 33
21 C.F.R. 820.81 33
21 C.F.R. 820.100 33
21 C.F.R. 820.101 33
21 C.F.R. 820.115 33
21 C.F.R. 820.116 33
21 C.F.R. 820.120 33
21 C.F.R. 820.121 33
21 C.F.R. 820.130 33
21 C.F.R. 820.160 33
21 C.F.R. 820.161 33
21 C.F.R. 820.162 33
21 C.F.R. 820.180 33
21 C.F.R. 820.181 33
21 C.F.R. 820.182 33
21 C.F.R. 820.184 33
21 C.F.R. 820.185 33
21 C.F.R. 820.195 33
21 C.F.R. 820.198 33
21 C.F.R. 895.25 24,31
21 C.F.R. 895.25(a) 24
21 C.F.R. 895.25(a)(3) 24
21 C.F.R. 895.25(b) 24
21 C.F.R. 895.25(d) 24
28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(9) 45

TABLE OF AUTHORITIES continued

Page

28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(10) 45
42 Fed. Reg. 30,383 (June 14, 1977) 48,49
43 Fed. Reg. 18,661 (May 2, 1978) 48,49
43 Fed. Reg. 31,508 (July 21, 1978) 37
58 Fed. Reg. 57,614 (Oct. 26, 1993) 34

OTHER AUTHORITIES

121 Cong. Rec. S 6161 (daily ed. Apr. 17, 1975) 42

Alexander Bickel, *The Least Dangerous Branch* (1962) 19

Arthur N. Levine, FDA Enforcement Manual (Apr. 1994) 44

Device Good Manufacturing Practices Manual, HHS Pub. No. FDA 87-4179 (Nov. 1987) 32

Device Labeling Guidance, FDA General Program Memorandum #G91-1 (Mar. 8, 1991) 22

FDA 510(k) Clearance Letter K914966 (May 13, 1992) 22

FDA Compliance Program Guidance Manual (Mar. 5, 1995) 33

FDA Draft Guidance for Format and Content for Premarket Notification 510(k) (Mar. 23, 1994) 22

FDA Enforcement Manual Monthly Bulletin (Nov. 1994) 33

H.R. 9984, 93 Cong., 1st Sess. (1973) 42

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) 2,26

TABLE OF AUTHORITIES continued

Page

Mark Herrmann & Geoffrey J. Ritts, *Preemption & Medical Devices: A Response to Adler & Mann*, 51 Food & Drug L.J. 1 (1996) 9,13,18

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BRIEF FOR CROSS-RESPONDENT MEDTRONIC, INC.

This case involves the construction of 21 U.S.C. 360k(a), the preemption provision of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Medtronic and plaintiffs have taken two markedly different approaches to that question of statutory interpretation. This Court's choice between those two approaches will go a long way toward deciding this case.

Medtronic's approach focuses carefully on the statutory language and structure, and uses legislative history and policy considerations only to reinforce the statute's text or to help clarify its terms. See Pet. Br. 12-49.[1] In contrast, plaintiffs' approach (and that of most of their amici) is dominated by policy arguments, often phrased in the form that a Congress reacting to incidents involving the Dalkon Shield *could not* have intended particular results (e.g., Cross-Pet. Br. 29); by inferences from the *silence* of legislative history (e.g., *id.* at 30); and by *subsequent* "legislative history" and subsequent congressional *inaction* on proposed legislation (e.g., *id.* at 33 n.12). When plaintiffs and most of their amici do pay attention to the statutory language, they do so only by misreading expansive language as if it contained words of narrow limitation. For example, they read the broad statutory phrase "any requirement applicable under this chapter to the device" as if it meant any *safety-ensuring* requirement, see U.S. Br. 19-20, and conclude that a requirement is *not* "applicable to the device" merely because it also applies to things other than the device, see Cross-Pet. Br. 41-42.

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[1] This brief uses the same abbreviations (such as MDA, FDCA, and 510(k) process) used in Medtronic's opening brief. In addition, in this brief "Pet. Br." refers to Medtronic's opening brief, "Cross-Pet. Br." refers to plaintiffs' opening brief, and any citations to amicus briefs use an abbreviated form of the name of the party listed first on the brief.

Plaintiffs' approach to statutory interpretation is not legitimate. This Court "assume[s] that the legislative purpose is expressed by the ordinary meaning of the words used," *United States* v. *James*, 478 U.S. 597, 604 (1986); is "not willing to narrow the plain meaning of * * * [a] statute on the basis of a gestalt judgment as to what Congress probably intended," *Garcia* v. *United States*, 469 U.S. 70, 78 (1984); and will not take the "extraordinary" step of "requir[ing] legislative history to *confirm* the plain meaning of" a statute, *Bourjaily* v. *United States*, 483 U.S. 171, 178 (1987). As the Court has explained, "no legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987) (per curiam).

Plaintiffs focus exclusively on the congressional intent to protect consumers from unsafe and ineffective devices and *completely ignore* the congressional intent to promote availability and innovation of devices by prohibiting state requirements through the preemption provision. Compare Cross-Pet. Br. 2-3, 11 with Pet. Br. 1-10 and U.S. Br. 2. By focusing on only one of Congress's several objectives, plaintiffs entirely disregard the congressional intent to enact a "balanced regulatory proposal," H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976), and thereby overlook the purpose of *the FDCA preemption provision*—enhancement of public health by preventing state regulation from stifling innovation of, and access to, critical medical technologies. See Pet. Br. 1-5, 46-49; PLAC Br. 4-8. The congressional balance of interests is manifest in the language of the preemption provision, which prohibits state device requirements "relat[ing] to * * * safety or effectiveness," even if the state requirements would be "more stringent" than applicable federal requirements. 21 U.S.C. 360k(a)(2), (b)(1).

Plaintiffs not only stress one congressional objective repeatedly to the exclusion of others, but also they overlook the *means* Congress selected to carry out the goal of protecting consumers from unsafe and ineffective devices. Plaintiffs incorrectly imply that the congressional intent to protect consumers necessarily requires compensation through tort remedies. But Congress instead chose to protect consumers by giving the FDA significant new authority to impose substantive safety and effectiveness requirements, remove dangerous devices from the market, and control market entry through premarket clearance processes. See Pet. Br. 5-10. Because the MDA substantially *enhanced* consumer protection by imposing new federal requirements, plaintiffs are simply incorrect in asserting that the statute's preemption of common law claims leaves consumers with less protection than they had before the MDA's enactment.[2]

Even if one were willing to join plaintiffs in speculating what Congress *could* or *could not* have intended, there would be no reason to doubt that Congress meant what it said in the encompassing words of the statute, i.e., meant to preempt *all* state "requirements"—including those imposed by the common law—that are "different from, or in addition to," *any* applicable FDCA requirement and that relate to safety or effectiveness *or* to another matter covered by an applicable FDCA requirement. Members of Congress thinking rationally about the *benefits* that thousands of safe and effective medical devices provide millions of consumers—and not just focusing obsessively on the well-

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[2] Attempting to minimize the significance of these comprehensive federal requirements, plaintiffs erroneously suggest (e.g., Cross-Pet Br. 35-36) that devices cleared through the 510(k) process put the public at risk through inadequate premarket scrutiny of safety and effectiveness. This assertion fundamentally contradicts their contention that Congress enacted the MDA as "landmark legislation" addressed solely to consumer protection. In any event, as Medtronic explained in detail in its opening brief, the statute created multiple safeguards applicable to 510(k) devices. See Pet. Br. 8-10, 23-27; see also HIMA Br. 3-22.

publicized problems of a *single* device, the Dalkon Shield—could easily conclude that the best approach to regulation was to concentrate it in one federal agency, capable of considering both costs and benefits, and not to allow states to supplement such intensive federal regulation with additional state "requirements," *especially* not state requirements imposed by ad hoc decisions applying the generalities of the common law to individual circumstances. Members of Congress also easily could be concerned about the effect of state regulation (including application of the common law) on product availability and innovation and on the resources of small medical device manufacturers (which typified the industry in 1976 and still do today). See MDMA Br. 4-7; HIMA Br. 22-29; Ctr. for Patient Adv. Br. 11-23. And the best possible evidence that Congress *did* act on these concerns is the words of the statute.[3]

Furthermore, it certainly is not unusual for Congress to protect the public with comprehensive federal regulation on the one hand while preempting state tort remedies on the other. See, e.g., *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992); *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658 (1993).[4] And this

[3] The presence of an exemption clause (21 U.S.C. 360k(b)) allowing states to supplement federal regulation, *but only when the FDA agrees that the supplemental regulation meets certain standards*, mitigates any possible harshness from the breadth of the basic preemption provision (*id.* § 360k(a)). Cf. Cal. Br. 15-17 (asserting that, under a broad reading of the preemption provision, a "state remains powerless" to protect its own citizens, but *completely ignoring* exemption provision).

[4] This Court's decision in *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), does not warrant a different conclusion. As the opinion makes clear, *id.* at 249-256, and as the Court subsequently has explained, "the decision in *Silkwood* was based in substantial part on legislative history suggesting that Congress did not intend to include in the pre-empted field state tort remedies for radiation-based injuries." *English* v. *General Elec. Co.*, 496 U.S. 72, 86 (1990). Equally inapposite is *United Constr. Workers* v. *Laburnum Constr. Corp.*, 347 U.S. 656 (1954). See Nat'l Conf. of State Legis. Br. 6, 27-28; TLPJ Br. 16-17; ATLA Br. 14, 24; PLC-MDL Br. 5-6, 19. This Court's resolution of the question presented in *Laburnum*—whether Congress's

(Footnote continued on next page)

Court often has found preemption "even when the state action purported to authorize a remedy unavailable under the federal provision." *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 55 (1987). At least since *San Diego Building Trades Council* v. *Garmon*, 359 U.S. 236 (1959), the law has been settled that "the States' salutary effort to redress private wrongs or grant compensation for past harm" cannot justify state intrusion into a federal regulatory system, even though "the state remedy ha[s] no federal counterpart." *Id.* at 247; see also *Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 584 (1981) ("A finding that federal law provides a shield for the challenged conduct will almost always leave the state-law violation unredressed."); *Gillespie* v. *United States Steel Corp.*, 379 U.S. 148, 154-155 (1964) (Jones Act preempts state law even though plaintiff had no cause of action under the Act).[5]

(Footnote continued from previous page)

assignment to the NLRB of exclusive jurisdiction over unfair labor practices precluded a common law damages action arising out of conduct that might qualify as such an unfair practice—rested on numerous factors that simply have no application to this case. See 347 U.S. at 664-669 (relying *inter alia* on "the language of the Act," its "legislative history" and prior decisions interpreting the statute as "leav[ing] much to the states.")

[5] In any event, contrary to plaintiffs' assertions, Congress *did* provide a federal remedy to compensate consumers for devices that present an unreasonable health risk because they were not properly designed or manufactured. The statute gives the FDA authority to issue orders requiring device manufacturers to repair the device, replace it with one that conforms to FDCA requirements, or refund its purchase price. This federal remedy also includes "any reasonable and foreseeable expenses." 21 U.S.C. 360h(b)(3). If the FDA does not issue the order on its own initiative, any affected person may petition the agency to take action. 21 C.F.R. 10.25, 10.30. Although the statutory remedy is more limited than tort recovery might offer, the provision of reasonable and foreseeable expenses could include the types of medical expenses that Mrs. Lohr alleges she incurred in this case. Thus, plaintiffs are wrong in asserting that preemption of their tort claims would deny them access to any remedy for a defective device.

Whatever policies and "presumptions" the parties and amici may advance,[6] in the end this case must turn on the plain wording of the statute, which "necessarily contains the best evidence of Congress' pre-emptive intent," *Easterwood*, 507 U.S. at 664. As we now show, the statutory language, as informed by this Court's decisions, demonstrates that the FDCA preempts plaintiffs' claims for failure to warn and defective manufacture.

SUMMARY OF ARGUMENT

I. Under this Court's opinion in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), common law damages actions establish state "requirements" subject to preemption under the MDA. Plaintiffs attempt to distinguish *Cipollone*, but ultimately they merely re-argue issues the Court already has resolved against them.

The language of the FDCA preemption provision encompasses state common law claims. The Court should reject—as the Solicitor General does—plaintiffs' argument that the use of the term "requirement" three times in the preemption provision preserves common law claims. Although modifiers indicate that the two references to federal requirements only concern positive law, there are no similar modifiers that limit state requirements to positive law. The statutory language also does not support plaintiffs' argument restricting preemption only to those state requirements that apply exclusively to devices.

In addition, the Court should reject—again, as the Solicitor General does—plaintiffs' argument that common law claims are not subject to the statutory exemption provision, and therefore are outside the scope of the preemption provision. The exemption provision does cover common law claims. Even if it did not, there is no basis in the statute for concluding that the absence of an exemption affects the scope of preemption under the statute. Furthermore, the limited "savings clause" set forth at 21 U.S.C. 360h(d) does not contemplate preservation of tort claims, because it easily can be read to refer to other types of state-law liability.

[6] Compare Nat'l Conf. of State Legis. Br. 6-7 (strong presumption against preemption) with GM Br. 19-23 (no presumption against preemption except in cases of "field" preemption).

II. The FDCA preempts plaintiffs' failure-to-warn claims. The FDCA establishes significant federal requirements governing product warnings through the 510(k) process, the prescription device labeling regulation, post-market warning requirements, and the FDCA's general misbranding provisions. These requirements have preemptive effect, because they are "applicable to the device" within the meaning of the FDCA preemption provision. The Court should reject plaintiffs' argument that these requirements are not preemptive because they are not "device-specific"; plaintiffs' construction has no basis in the statutory language.

Plaintiffs' claims for failure to warn are preempted because they would establish state duties "different from, or in addition to," the federal prescription device labeling regulation, the 510(k) requirements, and the general misbranding provisions of the FDCA. The premise of these claims is that warnings that comply with these federal requirements are inadequate, and that state common law requires different and additional warnings. In addition, the state duties that would be imposed by plaintiffs' claims are not the same as the standards imposed by the federal requirements, and that fact alone is enough to preempt them.

III. The FDCA also preempts plaintiffs' defective manufacturing claims. The FDA's Good Manufacturing Practice ("GMP") regulations and the 510(k) process impose significant federal manufacturing requirements. These requirements have preemptive effect, because they are "applicable to the device" within the meaning of Section 360k(a).

Plaintiffs' claims are preempted because they would establish state duties "different from, or in addition to," the GMP regulations and 510(k) requirements. The premise of these

claims is that a manufacturing process that complies with these federal requirements is inadequate, and that state common law requires a different process. In addition, the state duties that would be imposed by plaintiffs' claims are not the same as the standards imposed by the federal requirements, and that is enough to preempt the claims.

IV. The FDCA also preempts plaintiffs' claims to the extent that they rely on federal standards. According to plaintiffs, identical state and federal requirements are not "different from, or in addition to," each other. That interpretation, however, is flawed: it reads the statute as if it preempts only "different" state requirements, and thus renders completely superfluous the phrase "in addition to." Moreover, plaintiffs' interpretation is inconsistent with the structure and legislative history of the MDA and the congressional intent to establish uniform device requirements. Equally mistaken is the Solicitor General's submission that "remedies" do not constitute "requirements." Contrary to the government's assertion, the FDA has *not* "consistently, and reasonably" (U.S. Br. 9-10) read the term "requirement" to exclude remedies. In fact, the FDA on several occasions has indicated that "remedies" *are* a species of state "requirements."

ARGUMENT

The first and longest argument in plaintiffs' opening brief (Cross-Pet. Br. 14-34)—which also is the *sole* argument made by most of plaintiffs' amici—is a sweeping assertion that the FDCA preempts *no common law damages claims at all*. The Solicitor General disagrees, as do the FDA and nine courts of appeals. U.S. Br. 15-19 & n.12; Pet. Br. 37 n.19.[7] We show in Point I below that both this Court's *Cipollone* decision and the language and structure of the statute foreclose plaintiffs'

[7] One court of appeals agrees with plaintiffs. *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) (Ferguson, J.); see also *id.* at 1460-1462 (Reinhardt, J., concurring).

argument. Plaintiffs' next argument is that the common law claims preempted by the FDCA do not include the failure-to-warn and defective manufacturing claims in *this* case. Cross-Pet. Br. 34-45. We show in Points II (failure to warn) and III (defective manufacturing) that plaintiffs are wrong; the court of appeals correctly held these claims preempted.

Finally, plaintiffs argue briefly that they may escape preemption by recasting their state-law claims as claims relying on federal standards. Cross-Pet. Br. 45-47. A cryptic passage in the Solicitor General's brief likewise claims that the FDA has consistently interpreted the term "requirement" in Section 521(a) not to preempt state tort remedies—even though that interpretation was newly conceived for this case. We show in Point IV below that acceptance of these arguments would be inconsistent with Congress's carefully crafted remedial scheme and the language and purpose of the statute.[8]

I. COMMON LAW CLAIMS ESTABLISH STATE REQUIREMENTS SUBJECT TO PREEMPTION UNDER THE FDCA

A. This Court Should Reject Plaintiffs' Re-Argument of Issues Resolved in *Cipollone*

Medtronic's opening brief explains that under the holding in *Cipollone*, 505 U.S. 504 (1992), plaintiffs' claims would establish state "requirements" within the meaning of the FDCA preemption provision. See Pet. Br. 36-39. Plaintiffs understandably seek to distinguish *Cipollone*, but, as the Solicitor General

[8] Plaintiffs and their amici rely extensively on a recent law review article that argues that the FDCA does not preempt common law claims. See Robert S. Adler & Richard A. Mann, *Preemption & Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895 (1994). For a point-by-point response to that article, see Mark Herrmann & Geoffrey J. Ritts, *Preemption & Medical Devices: A Response To Adler & Mann*, 51 Food & Drug L.J. 1, 8-19 (1996) (page proof copies of which have been lodged with the Clerk).

explains, their arguments are "difficult to square with" that decision. U.S. Br. 15-19.

Plaintiffs assert that common law claims merely require manufacturers to compensate plaintiffs and "do not require manufacturers to take any action with respect to a device." Cross-Pet. Br. 20; see also ATLA Br. 5-10. That assertion contradicts the fundamental premise of the *Cipollone* holding, which is that common law regulates conduct in the same manner as statutes or regulations. As Justice Stevens explained in his plurality opinion, common law claims establish state "requirements" because "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." 505 U.S. at 521 (quoting *Garmon*, 359 U.S. at 247).[9]

Cipollone also disposes of plaintiffs' argument that there can be no preemption of their claims without an explicit statutory reference to extinguishment of tort remedies, Cross-Pet. Br. 18, 31. The Cigarette Act at issue in *Cipollone* contained no explicit reference to common law claims, yet the Court affirmed their preemption. See also *Easterwood*, 507 U.S. at 664 (affirming preemption of common law claims without explicit reference to such claims in express preemption provision).

Cipollone further forecloses plaintiffs' argument that their claims are preserved because they are not "establish[ed] or continue[d] in effect" by a state, Cross-Pet. Br. 21-22. There is no principled distinction between the terms of the FDCA and the language of the Cigarette Act at issue in *Cipollone*, which pre-

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9 The Court's analysis in *Cipollone* was consistent with earlier cases recognizing that exposure to common law claims compels manufacturers to change their conduct to avoid future liability. See, e.g., *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 495 (1987); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981).

empted requirements "imposed" under state law, *Cipollone*, 505 U.S. at 515. Similarly, this Court held in *Easterwood* that common law claims were preempted under a Federal Railroad Safety Act provision barring "[a] State" from "adopt[ing] or continu[ing] in force" certain railroad safety standards. 507 U.S. at 662 & n.2.

Finally, *Cipollone* rejects plaintiffs' assertion that the statute preserves their claims because its legislative history does not explicitly refer to preemption of tort actions, Cross-Pet. Br. 30.[10] In *Cipollone*, this Court affirmed preemption of common law personal injury claims, even though portions of the Cigarette Act's legislative history suggested that "Congress was primarily concerned with positive enactments by States and localities," 505 U.S. at 521 (opinion of Stevens, J.), and there was no explicit reference in the legislative history to common law damages actions, *id.* at 540 (opinion of Blackmun, J.). Because the Act's *language* "plainly reache[d] beyond" positive enactments, 505 U.S. at 521 (opinion of Stevens, J.), the Court held that common law claims were subject to preemption. Similarly, in *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 385 n.2 (1992), this Court held that the Airline Deregulation Act preempted state advertising standards, even though the statute's legislative history contained no statements specifically ad-

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10 There is no claim that the legislative history contains statements *negating* the conclusion that tort actions are preempted. Instead, plaintiffs explicitly rely on "[t]he legislative history's *silence* on preemption of damages remedies." Cross-Pet. Br. 30 (emphasis added). Some of plaintiffs' amici do purport to find evidence in individual legislators' statements or in committee reports that the FDCA does not preempt tort claims (e.g., TLPJ Br. 7-8 & nn.5-6; AARP Br. 4 n.1, 19 n.10), but they rely on materials associated with *subsequent* legislation, or even subsequent congressional inaction. Such materials have no probative value at all. See *Brown* v. *Gardner*, 115 S. Ct. 552, 557 (1994); *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 114 S. Ct. 1439, 1453 (1994); *Pension Benefit Guaranty Corp.* v. *LTV Corp.*, 496 U.S. 633, 650 (1990); *Patterson* v. *McLean Credit Union*, 491 U.S. 164, 175 n.1 (1989).

dressing state regulation of advertising. See also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 n.2 (1990) (statute can have effects not explicitly mentioned in its legislative history). In the present case, the Court also should conclude that the statutory language mandates preemption despite the silence of the legislative history.

B. The Language of the FDCA Preemption Provision Encompasses Common Law Claims

1. The Preemption Provision's Use of the Term "Requirement" Three Times Does Not Exclude State Common Law Claims

Plaintiffs contend that the term "requirement" in the FDCA preemption provision necessarily means the same thing each of the three times it appears. Because two of the three references are to federal requirements imposed solely pursuant to statute or regulation, plaintiffs argue that the single reference to state requirements is similarly limited, excluding common law claims. Cross-Pet. Br. 18-19. As the Solicitor General explains, plaintiffs' argument does not withstand scrutiny. U.S. Br. 17.

Like the Cigarette Act in *Cipollone*, the FDCA defines preempted state requirements according to their content and does not distinguish between common law and positive enactments. See *Cipollone*, 505 U.S. at 515. State requirements are preempted if they "*relate*[] [i] *to the safety or effectiveness of the device or* [ii] *to any other matter included in a requirement applicable to the device*" under the FDCA and fit the other terms of the preemption provision. 21 U.S.C. 360k(a)(2) (emphasis added). In contrast, the FDCA defines preemptive *federal* requirements with modifiers indicating their statutory and regulatory *source* rather than their subject matter. Thus, the FDCA describes a preemptive requirement as "*any requirement applicable under this chapter to the device*." *Id.* § 360k(a)(1) (emphasis added). As the Solicitor General notes, the obvious conclusion that federal requirements derive from regulations and statutory provisions rather than common law does not extend to

the state requirements, because the FDCA does not limit state requirements with any modifier referring to positive law. U.S. Br. 17; see also Herrmann & Ritts, *supra*, 51 Food & Drug L.J. at 8-9.

Finally, plaintiffs' construction of the FDCA preemption provision would lead to absurd results. Their distinction between common law and positive law is particularly untenable in a state like Florida, which has adopted common law doctrines *by statute*.[11] Furthermore, if preempted state requirements were limited to positive law, the FDCA would prohibit personal injury claims in states that have codified their tort doctrines[12] but preserve claims in states that have not. Plaintiffs' construction of the statute would establish an irrational pattern of liability exposure from state to state, undermining the congressional intent to establish uniform nationwide requirements for medical devices. See Pet. Br. 4-5. This Court should conclude that the FDCA's language does not support plaintiffs' untenable distinction between common law and positive law.

2. The FDCA Does Not Restrict Preemption to State Requirements That Apply Exclusively to Devices

Relying on an FDA regulation, plaintiffs assert that Section 360k(a) does not apply to common law claims because it pro-

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[11] See, e.g., *Coastal Petroleum Co.* v. *American Cyanamid Co.*, 492 So. 2d 339, 347 (Fla. 1986) ("In 1819, the territorial legislature of Florida adopted a statute declaring the common law of England to be of force in Florida. The statute, in modified form but unchanged as to substance, is still in effect * * *.") (Boyd, C.J., dissenting), cert. denied, 479 U.S. 1065 (1987).

[12] See, e.g., Conn. Gen. Stat. Ann. §§ 52-572m to 52-572q (West 1991); Ind. Code Ann. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996); La. Rev. Stat. Ann. §§ 9:2800.51 to 9:2800.59 (West 1991); Me. Rev. Stat. Ann. tit. 14, § 221 (West 1980); Miss. Code Ann. § 11-1-63 (Supp. 1994); Mont. Code Ann. § 27-1-719 (1993); N.C. Gen. Stat. §§ 99B-1 to 99B-11 (Michie 1995); Ohio Rev. Code Ann. §§ 2307.71 to 2307.80 (Baldwin 1996); S.C. Code Ann. §§ 15-73-10 to 15-73-30 (Law. Co-op. 1993).

hibits only those state requirements that apply exclusively to devices. Cross-Pet. Br. 19-21. As the Solicitor General explains, however, plaintiffs' argument is "strained as a grammatical matter," because the statutory language encompasses state requirements "of general applicability" such as tort duties. U.S. Br. 17-18. The Solicitor General's brief, in fact, flatly contradicts the FDA's previous interpretation. Compare U.S. Br. 18 (the language of the preemption provision "suggests that such a [preempted state] 'requirement' may be one *of general applicability*") (emphasis added) with 21 C.F.R. 808.1(d)(1) ("Section 521(a) does not preempt State or local requirements *of general applicability* where the purpose of the requirement relates * * * to *other products in addition to devices* * * *.") (emphasis added).[13]

Plaintiffs argue that claims asserting violations of generally applicable tort duties are not preempted because, under the statute, "only state *requirements* '*with respect to a device*' are candidates for preemption." Cross-Pet. Br. 19-20 (emphasis added). But plaintiffs' construction changes the order of words in the statutory language, thereby altering their meaning. Section 360k(a) provides that state requirements may not be "*establish[ed] or continue[d] in effect with respect to a device*" (emphasis added). Thus, the phrase "with respect to a device" modifies the verbs "establish" and "continue in effect" rather than the noun "requirement." As the Solicitor General notes, the statutory language indicates that the requirements could be established or continued in effect in other contexts not involving

[13] The Solicitor General's abandonment of the FDA's gloss on the statute wisely anticipated this Court's decision in *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996), which points out (slip op. 15) that "a statute may specifically relate to more than one thing" and that Congress's preemptive intent is not to be disregarded just because a statute relates to other things in addition to the subject cited in the statute.

devices; requirements therefore need not apply exclusively to devices to be preempted. U.S. Br. 18.[14]

Plaintiffs' interpretation also would "creat[e] an utterly irrational loophole." *Morales*, 504 U.S. at 386. For example, under their interpretation, the FDCA would preserve a general state product warning or manufacturing requirement not directed exclusively to devices, even if it directly conflicted with federal device warning or manufacturing requirements. But, as this Court noted in *Morales*, "there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute." *Ibid.* Plaintiffs' construction also would allow states to avoid preemption by the simple expedient of structuring their medical device statutes and regulations to apply to one or two other products (e.g., drugs) in addition to devices. Plaintiffs fail to explain why Congress would have wanted a regime that tolerates such conflicting state regulation and permits such easy circumvention of the preemption clause.[15] See also PLAC Br. 16-20.

[14] See also *Cipollone*, 505 U.S. at 515 (affirming preemption of claims under generally applicable common law doctrines as requirements *imposed* under state law *with respect to* the advertising or promotion of any cigarettes); *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817, 821 (1995) (affirming preemption of claims under generally applicable consumer fraud statute as state law *relating to* rates, routes, or services of any air carrier); *Morales*, 504 U.S. at 386 (preempting application of general consumer protection statutes to air carrier advertising).

[15] The Court should reject plaintiffs' assertion that it should defer to the agency pronouncements they cite to support their construction of the statute. Deference to agency interpretations is not appropriate in cases such as this, in which the intent of Congress is clear in the statute. *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (1984). Furthermore, the Solicitor General has resolved any doubt about the propriety of deference by abandoning the pronouncements cited by plaintiffs. The Solicitor General agrees with Medtronic that generally applicable common

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C. Other Provisions of the FDCA Support Preemption of Common Law Claims

Citing 21 U.S.C. 360k(b), which grants the FDA authority to exempt state requirements from preemption, plaintiffs argue that Congress could not have intended the exemption provision to apply to state requirements established through common law claims, because it is not practically feasible to grant exemptions for such requirements. They further reason that, if the exemption provision in subsection (b) does not encompass common law claims, neither does the preemption provision in subsection (a). Cross-Pet. Br. 24-27. As the Solicitor General explains, however, plaintiffs' assumption and conclusion are both invalid. See U.S. Br. 18-19.

Congress said nothing in subsection (b) to exclude common law duties. Medtronic agrees that it might be very difficult for a state to demonstrate that its common law duties meet the standards of subsection (b) and warrant an exemption. But that *practical* difficulty does not exclude common law duties from the broad statutory language. See U.S. Br. 18.[16]

Furthermore, even if subsection (b) excluded common law claims entirely, as plaintiffs suggest, there is nothing in the statute indicating that Congress intended to ensure the availability of an exemption for every type of requirement subject to preemption under subsection (a). As the Solicitor General notes, Congress may well have contemplated that the difficulties of granting an exemption for common law requirements exclude

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law duties are preempted if they are different from, or in addition to, applicable FDCA requirements. U.S. Br. 10-12, 15-19.

[16] It may be relatively rare for a state to apply for an exemption for common law doctrines, as plaintiffs note. Cross-Pet. Br. 24-27. Nonetheless, the FDA has never taken the position that exemptions for common law duties are unavailable, "and the FDA does not do so here." U.S. Br. 18 n.13.

them from subsection (b), even though they are subject to preemption under subsection (a). U.S. Br. 18-19.[17]

The Court also should reject plaintiffs' argument that 21 U.S.C. 360h contemplates preservation of tort claims against device manufacturers. See Cross-Pet. Br. 27-28. That section gives the FDA broad authority to issue administrative orders to remedy unreasonable public health risks created by medical devices. Section 360h(d) also states that compliance with one of these remedial orders does not affect other liability under state or federal law:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

This reference to federal or state liability is not necessarily a reference to personal injury tort claims, and a general reference to "liability" certainly does not indicate that all tort claims are beyond the reach of the preemption provision. Section 360h(d)

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[17] Congress's desire not to hamper the innovation of life-saving medical technologies, or to burden unduly the small manufacturers that make up this industry, is manifest in the overall design and structure of Section 360k, which includes both a very broad preemption provision and an exemption provision that grants discretion to the expert federal regulator to make exceptions if certain statutory criteria are satisfied. That design largely removes the onus from manufacturers to determine which state requirements are preempted, and places the burden instead on states to seek exemptions in cases of doubt. That structure also permits a single national decisionmaker—the FDA—to assess the incremental effect of multiple or successive exemptions on the cost and availability of particular devices. And it vests in the expert agency the authority—at least when the statutory criteria for an exemption are satisfied—to assess a state's assertions about the need for "different" or "addition[al]" safety and effectiveness requirements, as well as to weigh the benefits of such requirements against the burdens they would impose.

can easily be read as having nothing to do with tort liability, referring instead to state contractual liability for economic loss in disputes between device manufacturers, importers, distributors, and retailers arising from issuance of an agency remedial order.[18] The clause also could apply to state tort duties (whether or not codified by statute) that the FDA exempts from preemption. See pp. 16-17 *supra*. These readings of the statute respect the broad language of the FDCA preemption provision, consistent with this Court's decisions establishing that savings clauses "cannot in reason be construed as continuing * * * a common law right, the continued existence of which would be absolutely inconsistent with the provisions of [an] act." *Texas & Pac. Ry.* v. *Abilene Cotton Oil Co.*, 204 U.S. 426, 446 (1907); see also *Morales*, 504 U.S. at 384-385; GM Br. 16-17; Herrmann & Ritts, *supra*, 51 Food & Drug L.J. at 10-12.

II. THE FDCA PREEMPTS PLAINTIFFS' FAILURE-TO-WARN CLAIMS

Relying on different rationales, plaintiffs, their amici, and the Solicitor General all argue that, even if state "requirements" covered by Section 360k(a) can include common law claims, the failure-to-warn and defective manufacturing claims in this case are not preempted. Plaintiffs and their amici rest almost entirely on the notion (founded in an FDA regulation and *not* in the statute itself) that only "device-specific and subject-specific" federal requirements have any preemptive effect. Cross-Pet. Br. 39-44; see Calif. Br. 11-17; PLC-MDL Br. 7-14. The Solicitor General *rejects* that argument (U.S. Br. 18) but presents rea-

[18] For example, if the FDA orders a wholesale distributor to repair a retailer's shipment of defective devices under Section 360h(b), the retailer may still wish to sue the distributor for breach of contract. Section 360h(d) would allow the suit to proceed, with the value of the repaired devices being subtracted from any additional damages recovered. Cf. *Wolens*, 115 S. Ct. at 826 (claims under Illinois Consumer Fraud Act preempted, but savings clause preserved contractual remedies).

sons—which are rather opaque—why he believes plaintiffs' claims survive preemption nevertheless. U.S. Br. 22-28.

The reason for this disarray of rationales is not hard to fathom. Plaintiffs, their amici, and the Solicitor General are not willing to focus on the one sure guide to statutory interpretation: the words that Congress enacted. Attention to those simple words makes it quite easy to apply the preemption provision to this case—and to conclude that plaintiffs' claims are preempted.

The FDCA preemption provision is written in the following broad words:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, *any requirement applicable under this chapter to the device*, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a) (emphasis added). It is beyond rational debate—although both plaintiffs (Cross-Pet. Br. 34-38) and the Solicitor General (U.S. Br. 19-21, 22 n.16) continue to debate the point—that *any* FDCA requirement applicable to the device has preemptive effect. Thus, when the Solicitor General asserts that the 510(k) process has no preemptive effect at all because it "does not reflect a determination by the FDA that the device is safe and effective, much less a specific determination that the device's design is required to ensure its safety and effectiveness," U.S. Br. 19, he answers a question that the statute does not ask.[19] This Court is not called upon to decide how far the

[19] "No answer is what the wrong question begets * * *." Alexander Bickel, *The Least Dangerous Branch* 103 (1962). The Eleventh Circuit made

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510(k) process goes to ensure safety and effectiveness, but rather only whether it imposes a "requirement applicable under this chapter to the device."[20] And there is no possible doubt that it does, for reasons explained in our opening brief (Pet. Br. 30-36).[21]

The 510(k) requirements are not the only federal requirements that apply to the Model 4011 with preemptive effect. As we will now explain in detail, *several* federal "requirements" are preemptive, and plaintiffs' claims would establish state requirements that are "different from, or in addition to," those federal requirements and that relate to safety and effectiveness and other matters covered by the FDCA.

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the same error (Pet. App. 26a-27a), although it correctly held that plaintiffs' failure-to-warn and defective manufacturing claims are preempted.

[20] Even the preempted *state* requirement need only "relate[] to" safety or effectiveness (or another matter included in an applicable FDCA requirement). 21 U.S.C. 360k(a)(2). Congress did not apply even *that* modest limitation (see *Barnett Bank*, slip op. 12) to the *federal* requirement. See *id.* § 360k(a)(1). There is no textual basis for the Solicitor General's bold assertion that a preemptive federal requirement must not only relate to, but also *ensure*, safety and effectiveness. In any event, as Medtronic explained in its opening brief, the 510(k) process *does* impose significant safety and effectiveness requirements on the Model 4011. See Pet. Br. 19-30.

[21] The Solicitor General *himself* recognizes that anything referred to in other sections of the FDCA as a "requirement" must be a requirement for purposes of Section 360k(a), yet he ignores the logical consequence of that argument, which is that requirements imposed under the 510(k) process must be preemptive. Compare U.S. Br. 24 n.19 (conceding "that the GMPs impose 'requirement[s]' within the meaning of Section [360k](a)" because other sections of the FDCA refer to them as imposing "requirements") with Pet. Br. 31-32 (arguing, in a passage that the Solicitor General ignores, that Section 510(k) imposes "requirements" within the meaning of Section 360k(a) because other sections of the FDCA refer to it as imposing "requirements").

A. The FDCA Establishes Substantial Requirements for Product Warnings Concerning the Model 4011

1. The 510(k) Process Imposes Substantial Requirements Concerning Labeling Warnings

The 510(k) premarket clearance process imposes substantial requirements concerning labeling warnings for prescription devices such as the Model 4011.[22] It prevents marketing without FDA clearance, requires submission of significant information about the device for FDA review, and bars significant changes without further FDA clearance. See Pet. Br. 19-30. All of these requirements apply with full force to the Model 4011's labeling.[23]

Manufacturers must submit proposed labeling for agency review to obtain 510(k) clearance. 21 C.F.R. 807.87(e).[24] The FDA reviews the labeling as part of its determination of sub-

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[22] The FDCA distinguishes the term "label" from the broader term "labeling." "Label" means "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. 321(k). "Labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). Under the FDCA, "labeling" includes a broad variety of product literature (including technical manuals explaining product use and promotional materials), even if they do not physically accompany distribution of the device. See *Kordel* v. *United States*, 335 U.S. 345 (1948).

[23] Plaintiffs fail to mention most of these requirements and incorrectly characterize the 510(k) process as a notification provision. See Cross-Pet. Br. 5, 34-35.

[24] Plaintiffs cite a GAO report for the proposition that the FDA may clear devices for marketing without submission of labeling. Cross-Pet. Br. 42. The report does not support plaintiffs' assertion, because it indicates only that some 510(k) applications lack labeling when the FDA initially *receives* them. U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved 62 (GAO/PEMD-88-14, Aug. 1988). The FDA's authority to ask for additional information before granting premarket clearance (see 21 C.F.R. 807.87(k)) resolves such deficiencies. In any event, Medtronic did submit labeling in its 510(k) application concerning the Model 4011.

stantial equivalence. See, e.g., FDA Draft Guidance for Format and Content for Premarket Notification 510(k) (Mar. 23, 1994) at A-8, A-13 ("Substantial equivalence is to be established with respect to, but not limited to, intended use, design; energy used/delivered, materials, performance, safety, effectiveness, *labeling*, and other applicable characteristics.") (emphasis added). For devices in which the inclusion of specific warnings is critical to a finding of substantial equivalence, the FDA's review "includes an evaluation of the compliance of the proposed labeling, or portions thereof, with applicable requirements under 21 C.F.R. Part[] 801." Device Labeling Guidance, FDA General Program Memorandum #G91-1 (Mar. 8, 1991) at 2. The 510(k) review also may lead the agency to *prohibit* certain warnings that it deems inappropriate. See, e.g., FDA 510(k) Clearance Letter K914966 (May 13, 1992) (barring warnings regarding use of bone screw in the spine).

After marketing begins, the 510(k) requirements also bar manufacturers from changing labeling warnings in a manner that could affect safety or effectiveness of the device significantly unless the FDA clears the labeling changes through another 510(k) review. See 21 C.F.R. 807.81(a)(3)(i). For example, 510(k) review is required for labeling changes that arise from significant new issues of safety or effectiveness not evident at the time of initial FDA clearance. If the manufacturer makes significant labeling changes without FDA clearance, the agency may initiate an enforcement action to stop distribution of the device. Cf. Complaint, *United States* v. *11,307 Boxes*, No. 93-574 (S.D. Fla. filed Mar. 24, 1993) (seizure complaint alleging significant changes of labeling in violation of 21 C.F.R. 807.81(a)(3)).

2. The Prescription Device Labeling Regulation Imposes Substantial Warning Requirements

The FDA's prescription device labeling regulation, 21 C.F.R. 801.109, imposes substantial requirements on the Model 4011, contrary to plaintiffs' suggestion that it does "little more

than tell manufacturers to list * * * warnings * * * and the like." Cross-Pet. Br. 43. The regulation requires that the labeling disclose information concerning use of the prescription device, "including indications, effects, routes, methods, and frequency and duration of administration." 21 C.F.R. 801.109(c). In addition, the regulation requires the manufacturer to include the following warnings on the labeling so that physicians are adequately informed of

> any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented.

Ibid. The regulation does, however, allow manufacturers to omit those directions, hazards, and warnings that are "commonly known to practitioners licensed by law to use the device." *Ibid.*

Furthermore, under the regulation, devices such as the Model 4011 may be sold "only to or on the prescription or other order of [a] practitioner for use in the course of his professional practice." 21 C.F.R. 801.109(a)(2); R1-37-Exh.1, at 3-4. By definition, prescription devices are those for which there cannot be adequate directions for use by laypersons. 21 C.F.R. 801.109. To ensure appropriate physician oversight, the regulation requires manufacturers to include a legend restricting the device "to sale by or on the order of a physician." 21 C.F.R. 801.109(b)(1); R1-37-Exh.1, at 3.

The FDA's enforcement activities underscore the significance of these requirements. As the Eleventh Circuit noted, "the FDA's record of taking action against mislabeled devices forecloses the argument that the Act's labeling requirements lack substantive 'bite.' " Pet. App. 33a.; see, e.g., *United States* v. *An Article of Device*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984) (seizure action for violation of 21 C.F.R. 801.109); *United States* v. *Articles of Device*, 426 F. Supp. 366 (W.D. Pa. 1977) (same).

3. The FDCA and Related Regulations Give the FDA Substantial Authority to Require Additional Warnings After Marketing Begins and Prohibit Distribution of Devices with Inadequate Warnings

Although the FDA has not required warnings for the Model 4011 beyond those in the labeling cleared through the 510(k) process, the agency does have substantial authority to require additional warnings once marketing begins. Under 21 C.F.R. 895.25, the FDA may require manufacturers to change a device's labeling to contain statements, notices, or warnings if the device presents unreasonable public health risks. 21 C.F.R. 895.25(a), (b). The FDA has authority to dictate when the labeling change must occur and how long it must last. *Id.* § 895.25(a)(3), (b). If the manufacturer does not carry out the required change in labeling, the FDA has authority to initiate a proceeding to ban the device, 21 U.S.C. 360f; 21 C.F.R. 895.25(d), or take the device off the market through its other broad remedial powers. See, e.g., 21 U.S.C. 360h(e) (cease and desist authority), 334 (seizure authority). The FDA also has power to require manufacturers to issue notifications (separate and apart from any labeling) warning the public about significant health risks it detects through a variety of sources, including manufacturers' mandatory reports of device malfunctions, serious injuries, and deaths. See 21 U.S.C. 360h(a), (e), 360i.

The FDCA also establishes general prohibitions on distribution of devices rendered unsafe by inadequate warnings. A device is "misbranded" under the statute if the warnings in its labeling are not adequate such that the device may be dangerous to health or if use in accordance with the labeling renders it dangerous to health. 21 U.S.C. 352(f)(2), 352(j). A device also is misbranded if its labeling is "false or misleading" because it omits material warnings. 21 U.S.C. 352(a), 321(n). Manufacturers of misbranded devices are subject to criminal prosecution and actions for seizure, injunction, and civil penalties, among other sanctions. See *id.* §§ 331-334.

B. The Federal Warning Requirements Have Preemptive Effect Because They Are "Applicable to the Device"

"[A]ny requirement applicable under [the FDCA] to the device" has preemptive effect. 21 U.S.C. 360k(a)(1). The plain meaning of that language encompasses all of the federal warning requirements described above. In addition, two other sections characterize the 510(k) requirements as "appl[icable] to the device" (see Pet. Br. 30-32). One of those other sections also characterizes the prescription device labeling regulation and general misbranding provisions as federal requirements "appl[icable] to the device." 21 U.S.C. 360j(a).[25] These federal requirements are therefore preemptive.

Rather than analyzing whether the federal warning requirements are "applicable to the device," as the statute mandates, plaintiffs examine whether they apply *exclusively* to a *single* type of device; under plaintiffs' construction of the statute, only "device-specific" requirements are preemptive. Cross-Pet. Br. 39-42; see also, e.g., Calif. Br. 11-17; PLC-MDL Br. 7-14. But nothing in the language of the preemption provision limits the phrase "any requirement applicable under [the FDCA] to the device" to those requirements that apply exclusively to a single type of device. The court of appeals correctly held that the language of Section 360k(a) "does not suggest that the requirements themselves must mention the particular device in question" in order to have preemptive effect. Pet. App. 19a.[26]

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[25] Section 360j(a) unequivocally establishes that the requirements of Section 502 of the FDCA are applicable to the device unless the FDA changes their applicability or other statutory provisions not relevant to this case conflict with them. The general misbranding provisions are set forth in Section 502 of the FDCA, 21 U.S.C. 352, and the prescription device labeling regulation was promulgated under FDCA § 502(f)(1), 21 U.S.C. 352(f)(1). See 21 C.F.R. 801.109.

[26] Plaintiffs cite the Fifth Circuit's decision in *Moore* v. *Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), for the proposition that federal

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Furthermore, plaintiffs' construction of the preemption provision is inconsistent with the congressional intent to enact a "general prohibition on non-Federal regulation." H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). If preemption were limited to device-specific federal requirements, relatively trivial conflicts between federal and state law (relating only to a single device) would be prohibited, while the statute would leave intact significant broad-based conflicts (relating to numerous devices). For example, federal warning requirements uniquely applicable to pacemaker leads would preempt state regulations imposing different warning requirements, yet federal warning requirements governing broad categories of devices would not preempt similarly broad state laws. Indeed, because there are fewer than two dozen substantive device-specific FDA regulations, and only one device-specific requirement in the statute, plaintiffs' interpretation would wholly eviscerate the FDCA preemption provision.

In addition, plaintiffs' interpretation would make preemption turn on whether the applicable federal regulation explicitly refers to the device at issue—an absurd result with no support in the statutory language. Plaintiffs' interpretation would severely handicap the FDA in promulgating a preemptive regulation, which would need to list every device to which it applied, even if it affected thousands of devices.

Lacking support for their position in the statutory language, plaintiffs retreat to FDA interpretations to justify their construction of the FDCA preemption provision. But the Solicitor General indicates that federal requirements *need not* be device-

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requirements do not preempt state law unless they are device-specific. See Cross-Pet. Br. 14, 31, 43. But the Fifth Circuit has rejected the *Moore* holding, stating that, "since *Moore*, it has become clear that these regulations need *not be device-specific*; they need only apply generally to the device at issue" to preempt state law. *Feldt* v. *Mentor Corp.*, 61 F.3d 431, 436 (5th Cir. 1995) (emphasis added).

specific to be preemptive. The Solicitor General's brief does not even *refer to* the agency interpretations that are the premise for plaintiffs' argument and concedes that the GMP regulations, which apply to thousands of devices, are federal "requirements" under the FDCA preemption provision. See U.S. Br. 24 n.19, 25 n.20.

Although the Solicitor General correctly refutes plaintiffs' analysis, he nonetheless joins their conclusion that there are no preemptive federal requirements applicable to plaintiffs' failure-to-warn claim. U.S. Br. 27-28. The Solicitor General asserts that the 510(k) requirements are not preemptive because they do not reflect a "determination" that the device is safe and effective or an "approval" of the adequacy of the device's labeling (U.S. Br. 19-20, 28). As we have explained (pp. 19-20, *supra*), however, that approach lacks *any* basis in statutory text. And the Solicitor General is silent on the question whether the general misbranding provisions of the FDCA are federal "requirements" within the meaning of Section 360k(a), and he does not even refer to the prescription device labeling regulation, which the Eleventh Circuit relied on as the sole basis for affirming preemption of plaintiffs' claims. U.S. Br. 27-28; see Pet. App. 32a-33a. The Solicitor General simply has not asked the right question, and there is no reason for the Court to accept his analysis.

C. Plaintiffs' Failure-to-Warn Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011

Because common law claims establish state "requirements" potentially subject to preemption, and "any" applicable FDCA requirement can have preemptive effect, all that is left for plaintiffs to argue is that their tort claims would not impose requirements "different from, or in addition to," the applicable FDCA "requirement[s]" such as the warning requirements

described above.[27] But the failure-to-warn claims *would* impose different and additional requirements.

Plaintiffs' first theory of liability is that Medtronic gave inadequate warnings to Mrs. Lohr (as distinguished from her physician). R1-3-2; Cross-Pet. Br. 9.[28] The claims alleging failure to warn Mrs. Lohr are preempted, because *any* state-law requirement to warn lay users is "different from, or in addition to," the prescription device labeling regulation. The FDA's regulation defines the Model 4011 as a prescription device—whose distribution is prohibited without a prescription—precisely because adequate directions for lay use are *not possible to prepare* and laypersons cannot adequately understand the risks of its use, regardless of the warnings issued. See 21 C.F.R. 801.109. Yet plaintiffs' claim is that Medtronic should have provided additional warnings directly to Mrs. Lohr. The claim is preempted because it would establish a state requirement "different from, or in addition to," the FDA's regulation, which "exempt[s] [prescription] devices from the requirement that there be directions to a layperson on how to use the product safely." *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13, 18 (1st Cir. 1994).[29]

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[27] Plaintiffs erroneously assert that the state requirements must *conflict* with federal requirements to be preempted. See Cross-Pet. Br. 13.

[28] Although plaintiffs assert a claim for failure to warn Mrs. Lohr, no such claim even exists under Florida law. Florida has adopted the "learned intermediary" doctrine, which holds that any duty to warn about a medical device flows to the doctor and not to the patient. See, e.g., *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511 (S.D. Fla. 1990).

[29] Plaintiffs' claims for failure to warn Mrs. Lohr are preempted for the additional reason that the FDA has the exclusive authority to require notification to patients that they are using a device that puts them at risk. The FDCA accords the FDA discretion, based on its scientific expertise, to determine whether patients should be notified, or whether "notice to such individuals would present a greater danger to the health of such individuals than no such notification." 21 U.S.C. 360h(a). The statute grants the agency this authority, because in a variety of contexts, warning of device risks

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Plaintiffs' second theory of liability is that Medtronic gave inadequate warnings to Mrs. Lohr's physician. The claims asserting this theory also are preempted. First, Florida common law duties to warn the physician are "different from, or in addition to," the requirements of the prescription device labeling regulation. The regulation requires warnings of all "relevant" hazards but also allows omission of warnings if these risks are "commonly known to practitioners licensed by law to use the device." 21 C.F.R. 801.109(c). In contrast, the Florida duty is to provide "fair and adequate" warnings of the device's "inherent * * * dangerous propensities." See, e.g., *Stanley Indus., Inc.* v. *W.M. Barr & Co.*, 784 F. Supp. 1570, 1574 (S.D. Fla. 1992).[30] This duty (premised on the "inherent dangers" of a device) imposes a different standard than federal law, which requires "any relevant" warnings. Furthermore, the Florida duty could *require* warnings that the federal requirement *omits* because practitioners are commonly aware of the risks the warnings describe. 21 C.F.R. 801.109. As a result, the Florida duty is "different from, or in addition to," federal requirements.[31]

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threatens the health of patients, who may be frightened into abandoning use of a life-sustaining device or suffer psychological trauma from a notification.

[30] Plaintiffs assert failure-to-warn theories under both their negligence and strict liability causes of action. Although Florida law recognizes claims for failure to warn under both negligence and strict liability doctrines, the Florida courts have not drawn clear distinctions between the substantive duties imposed by the two types of claims. See, e.g., *Prather* v. *Upjohn Co.*, 797 F.2d 923, 926 (11th Cir. 1986); *Baione* v. *Owens-Illinois, Inc.*, 599 So. 2d 1377, 1378-79 (Fla. Dist. Ct. App. 1992). For purposes of preemption analysis, therefore, plaintiffs' negligence and strict liability failure-to-warn claims should be treated as one.

[31] Three courts of appeals in addition to the court below have cited the prescription device labeling regulation as a basis for FDCA preemption of state common law claims alleging failure to warn. See Pet. App. 33a; *Mendes* v. *Medtronic, Inc.*, 18 F.3d at 18; *Duvall* v. *Bristol-Myers-Squibb Co.*, 65

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Second, the failure-to-warn claims are preempted by the general misbranding requirements of the FDCA barring inadequate warnings. The Solicitor General argues that the generality of the misbranding provisions makes it very difficult to determine whether they impose standards different from plaintiffs' claims. See U.S. Br. 28.[32] That argument is illogical. Plaintiffs' complaint does not assert that Medtronic has violated the federal misbranding provisions, yet it does claim that the common law duty to warn has been breached. R1-3. Plaintiffs' claims therefore rest on the premise that compliance with the federal standard is insufficient, and that Florida tort law required additional and different warnings. By challenging the sufficiency of the federal standard, the state tort duty is *by definition* different, and the claims are preempted. Cf. *McDermott* v. *Wisconsin*, 228 U.S. 115, 132 (1913) (general misbranding provision in FDCA predecessor statute impliedly preempted state food labeling requirement).

Finally, plaintiffs' claims are preempted by the 510(k) requirements. By reviewing labeling submitted in the 510(k) application and clearing the device for marketing, the FDA made the decision that the Model 4011 can be marketed with the labeling submitted, and that Medtronic cannot change the labeling in a manner that could significantly affect safety or effectiveness without further FDA review and clearance. See, e.g., *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d at 399-400 ("[F]or all intents and purposes, [manufacturer] is required to continue to * * * label the device as proposed in its original 510(k) Notification."). Furthermore, the FDA has not exercised its

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F.3d 392, 399 (4th Cir. 1995), petition for cert. pending, No. 95-1010; *Feldt* v. *Mentor Corp.*, 61 F.3d at 436.

[32] One of the misbranding requirements the Solicitor General cites (relating to adequate directions for use) does not apply to the Model 4011 because it is a prescription device. See U.S. Br. 27; 21 C.F.R. 801.109 (exempting prescription devices from requirement to provide adequate directions for use).

authority to require additional warnings after it cleared the Model 4011 for marketing. See 21 U.S.C. 360h(a), (e); 21 C.F.R. 895.25. In contrast, plaintiffs claim that the labeling cleared by the FDA is inadequate, and that Florida common law required Medtronic to give different, and additional, warnings. Section 360k(a) preempts such claims.[33]

III. THE FDCA PREEMPTS PLAINTIFFS' DEFECTIVE MANUFACTURING CLAIMS

In discussing the defective manufacturing claims—as in discussing the labeling claims—plaintiffs, their amici, and the Solicitor General ask the wrong question and, predictably, get the wrong answer. *Numerous* federal requirements govern manufacturing, and plaintiffs' claims would impose different and additional requirements under state law. They are therefore preempted.

[33] Because the state duty would require Medtronic to change its warnings and the federal requirements bar such changes without FDA clearance, the failure-to-warn claims would establish requirements in direct conflict with federal law. Like the design claims discussed in Medtronic's opening brief, see Pet. Br. 46 n.24, the failure-to-warn claims would be impliedly preempted even if this Court were to conclude that they are not expressly preempted. See, e.g., *English* v. *General Elec. Co.*, 496 U.S. 72, 79 (1990) (state law is impliedly preempted if "it is impossible for a private party to comply with both state and federal requirements"); *Freightliner Corp.* v. *Myrick*, 115 S. Ct. 1483, 1488 (1995) (existence of an express preemption provision does not foreclose implied preemption arising from actual conflict between federal and state law). Plaintiffs concede that implied preemption doctrine could invalidate their claims under some circumstances. Cross-Pet. Br. 23 n.6. And this Court recently has clarified that implied preemption doctrine applies in significantly broader circumstances than plaintiffs acknowledge. There is implied preemption not only when a federal statute *commands* actions that a state forbids, but also when "the Federal Statute authorizes * * * activities that the State * * * forbids." *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996), slip op. 5.

A. The FDCA Establishes Substantial Manufacturing Requirements for the Model 4011

1. The GMP Regulations Impose Significant Manufacturing Requirements

The GMP regulations impose significant controls on device manufacture, contrary to plaintiffs' suggestion that they are trivial requirements, "little more than common-sense standards for the production of any product." Cross-Pet. Br. 44.

The FDCA authorizes the FDA to prescribe regulations "requiring that the methods used in, and the facilities and controls used for," the manufacture of a device "conform to current good manufacturing practice * * * to assure that the device will be safe and effective and otherwise in compliance with [the Act]." 21 U.S.C. 360j(f)(1)(A). Although the FDA is ultimately responsible for promulgating these GMP regulations, the statute establishes an expert advisory committee to formulate them. *Id.* § 360j(f)(1)(B). The statute requires that the advisory committee be composed of nine members chosen from local, state, or federal government, the device industry, the health professions, and the general public. *Id.* § 360j(f)(3).[34] These varying interests effectuate the congressional intent by formulating requirements strict enough to ensure safety and effectiveness, but not so strict that they would be "likely to retard innovation, reduce efficiency, and hinder cost control." Device Good Manufacturing Practices Manual, HHS Pub. No. FDA 87-4179 (Nov. 1987) at iv.

The GMP requirements that emerge from this regulatory structure establish critical quality assurance standards for the

[34] The statute also ensures broad public participation in the formulation of manufacturing requirements by mandating that the FDA must afford an opportunity for an oral hearing before the agency may promulgate proposed GMP regulations. *Id.* § 360j(f)(1)(B)(ii); 21 C.F.R. 15.1(b). After the regulations are proposed, the public has additional opportunities to participate through notice and comment rulemaking procedures.

medical device industry. These regulations require implementation of a quality assurance program covering all aspects of product manufacture. 21 C.F.R. 820.5. The GMP regulations establish requirements governing training, environmental control, and sanitation (*id.* §§ 820.25, .46, .56); equipment (*id.* §§ 820.60, .61); control of components (*id.* §§ 820.80, .81); production and process controls (*id.* §§ 820.100, .101, .115, .116); packaging and labeling controls (*id.* §§ 820.120, .121, .130); and inspection of finished devices (*id.* §§ 820.160, .161). Documented investigations of device failures also are required under the GMP regulations. *Id.* § 820.162. In addition, record-keeping requirements established in the GMP regulations apply to manufacture of devices. *Id.* §§ 820.180, .181, .182, .184, .185, .195, .198.

There certainly would be no need for the elaborate advisory committee structure described above if the plaintiffs' minimalization of the GMP regulations (Cross-Pet. Br. 44) were correct. In fact, the complexities of the GMP regulations have required the agency to issue hundreds of pages of guidance documents to aid its own investigators and industry in applying the quality assurance standards involved. See, e.g., Device Good Manufacturing Practices Manual, *supra*; FDA Compliance Program Guidance Manual, Transmittal No. 95-30 (Mar. 4, 1995). Furthermore, policing the GMP regulations has become a major thrust of the FDA's compliance program. Frequently, the majority of agency "warning letters" threatening enforcement actions derive from GMP issues, see, e.g., FDA Enforcement Manual Monthly Bulletin at 6 (Nov. 1994), and the FDA often initiates litigation to enforce the regulations, see, e.g., *United States* v. *Undetermined Quantities of Various Articles*, 800 F. Supp. 499 (S.D. Tex. 1992). As the court below properly explained, the agency's enforcement activity "foreclose[s] any suggestion that the GMP regulations are hortatory and without substantive effect." Pet. App. 31a.

2. The 510(k) Process Imposes Significant Manufacturing Requirements

Although the FDA's regulations do not explicitly require submission of manufacturing information in an original 510(k) application, the manufacturing process for a marketed device may not be changed in a manner that could significantly affect safety or effectiveness without 510(k) clearance. 21 C.F.R. 807.81(a)(3)(i).

The FDA has recognized that the 510(k) substantial equivalence requirements are inextricably linked to the GMP requirements in assuring reasonable safety and effectiveness of devices such as the Model 4011. Because the processes under which a device is manufactured fundamentally affect its safety and effectiveness, "both a change in manufacturing processes and a violation of [the GMP regulations] may have a significant impact on the question of substantial equivalence." 58 Fed. Reg. 57,614 (Oct. 26, 1993). As a result, the agency has concluded that a device that is manufactured under processes that constitute significant GMP violations "does not satisfy the criteria for a finding of substantial equivalence" under the FDCA. *Ibid.* The agency therefore enforces both 510(k) and GMP requirements to control device manufacturing.

B. The Federal Manufacturing Requirements Have Preemptive Effect Because They are "Applicable to the Device"

As the discussion at pages 25-27 *supra* explains, any FDCA requirement is preemptive as long as it is "applicable to the device." The 510(k) and GMP requirements described above easily fit within this phrase. In addition, Medtronic's opening brief and the discussion at page 25 *supra* also explain that two other sections of the FDCA refer to the 510(k) requirements as applicable to the device. See Pet. Br. 31-32. One of the same two sections also refers to the GMP requirements established under FDCA § 520(f) (21 U.S.C. 360j(f)) as "appl[icable] to the device," confirming their status as preemptive requirements. See

id. § 360c(d)(2)(A). See also U.S. Br. 24 n.19 (GMP regulations are "requirements" within the meaning of the FDCA preemption provision).

C. Plaintiffs' Defective Manufacturing Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011

Like the failure-to-warn claims discussed above, plaintiffs' defective manufacturing claims would establish state requirements "different from, or in addition to," applicable federal manufacturing requirements and meet all other criteria mandating preemption under the FDCA.

1. The GMP Requirements Preempt Plaintiffs' Defective Manufacturing Claims

Plaintiffs' defective manufacturing claims are preempted, because they would establish requirements "different from, or in addition to," the GMP regulations. Plaintiffs' complaint does not assert that Medtronic has violated the GMP regulations, but it does allege that the company violated the Florida negligence and strict liability standards. R1-3. The premise of plaintiffs' claims therefore is that a device manufactured in accordance with the GMP regulations is not sufficiently safe, and that Medtronic should have used a different manufacturing process. By asserting that Medtronic is exposed to state liability despite its compliance with the GMP regulations, plaintiffs' manufacturing claims necessarily would establish state requirements different from, and in addition to, those federal requirements.[35]

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[35] The court below and four other courts of appeals have held that the GMP regulations preempt defective manufacturing claims. See Pet. App. 31a; *Mendes* v. *Medtronic, Inc.*, 18 F.3d at 19; *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995); *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d at 399; *Feldt* v. *Mentor Corp.*, 61 F.3d at 436.

Nonetheless, the Solicitor General argues that there is no way to know whether plaintiffs' manufacturing claims would establish state requirements different from, or in addition to, the GMP requirements, because the federal requirements are phrased in general language that may *overlap* with state tort duties. U.S. Br. 22-25. Although the state and federal requirements may overlap to some extent, there also are areas in which they diverge, such as in the present case, in which plaintiffs allege that Medtronic should pay common law damages despite its compliance with the GMP regulations. As long as the state and federal requirements contain *some* differences, they are "different from" each other, even if they contain some similarities as well. See also Point IV, *infra*.

Furthermore, a comparison of the state and federal requirements at issue confirms their differences. First, plaintiffs' strict liability manufacturing claim would establish a state-law requirement different from the GMP requirements. Under Florida law, a manufacturer is subject to strict liability for distributing a product in a defective condition unreasonably dangerous to foreseeable users and bystanders. *Witt* v. *Norfe, Inc.*, 725 F.2d 1277, 1278 (11th Cir. 1984). In contrast, a manufacturer is liable for producing devices in violation of the GMP regulations even if those devices have no defects and are not at all dangerous to the user. See, e.g., *United States* v. *789 Cases*, 799 F. Supp. 1275, 1286 (D.P.R. 1992) (the FDA need not prove that the devices have defects or cause harm to prove GMP violations). The reason defects and dangers need not be shown is that the GMP regulations have a preventive purpose and are intended to "build in" quality prospectively to minimize the possibility of a defective device. Cf. 43 Fed. Reg. at 31,509 (July 21, 1978) (preamble to GMP regulations).

Second, plaintiffs' negligent manufacturing claim would establish state-law requirements different from the GMP requirements. The state-law duty underlying plaintiffs' negligence claim is a standard of reasonable care in product manufacture, imposed so that products will be reasonably safe for use in a

foreseeable manner. See, e.g., *Witt* v. *Norfe, Inc.*, 725 F.2d at 1278. In contrast, the GMP requirements derive not from what is "reasonable" but instead from "basic principles of quality assurance" that "have as their goal the production of articles that are fit for their intended uses." 43 Fed. Reg. at 31,509. The FDA explains those principles as follows (*ibid.*):

> (1) Quality, safety, and effectiveness must be designed and built into the product; (2) quality cannot be inspected or tested into the finished product; (3) each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications.

At the time the agency first promulgated the GMP regulations, device manufacturers had not yet adopted adequate quality assurance programs. Some firms had no programs at all, and the FDA estimated that the firms that did have programs were complying only with about half of the quality assurance requirements established through the GMP regulations. *Ibid.* As a result, the GMP regulations imposed new and different requirements on manufacturers that had been governed by common law duties before enactment of the MDA. There is no basis whatsoever for suggesting that the GMPs and the common law (which governed device manufacturers before 1976) are identical.

Finally, preemption of plaintiffs' manufacturing claims under the GMP requirements is consistent with the federal statutory structure. The FDCA assigns an expert advisory committee the responsibility for formulating manufacturing requirements. See pp. 32-33, *supra*. In contrast, plaintiffs' common law claims would allow a state judge and jury to determine the methods by which the Model 4011 lead should be manufactured. Preemption of those claims reserves implementation of manufacturing requirements to the federal government in accordance with the statutory procedures, as Congress intended.

2. The 510(k) Requirements Preempt Plaintiffs' Defective Manufacturing Claims

Plaintiffs' claims based on alleged manufacturing defects also are preempted because of the 510(k) requirements described above. Plaintiffs assert that Medtronic's manufacturing process was inadequate, and that it should have used a different process to produce a safer device. On the other hand, the FDCA prohibits the manufacturer of a device cleared through the 510(k) process from changing its manufacturing process in a way that could affect safety or effectiveness significantly without obtaining additional 510(k) clearance. 21 C.F.R. 807.81(a)(3)(i). State requirements that would be imposed through plaintiffs' manufacturing claims therefore are preempted under section 360k(a), because they are different from, or in addition to, the federal regulation requiring FDA clearance for manufacturing changes.[36]

IV. EVEN IF BASED ON FEDERAL STANDARDS, PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD IMPOSE REQUIREMENTS THAT ARE "DIFFERENT FROM, OR IN ADDITION TO," APPLICABLE FEDERAL REQUIREMENTS

In holding that plaintiffs' failure-to-warn and defective manufacturing claims are preempted, the court of appeals stated that "preemption under the MDA cannot be defeated by a common-law suit alleging a violation of the [federal] statutory standards." Pet. App. 13a-14a. A contrary result would permit lay juries, rather than the expert federal agency, to determine such complex issues as whether a medical device's "labelling and packaging information is incomplete or inaccurate, and if so what label changes, if any, should be made." Pet. App. 13a

[36] This conflict between state and federal law also invalidates plaintiffs' defective manufacturing claims under the implied preemption doctrine. See p. 31 n. 33 *supra*.

(quoting *Papas* v. *Upjohn Co.*, 985 F.2d 516, 519 (11th Cir.), cert. denied, 114 S. Ct. 300 (1993)). The Eleventh Circuit's conclusion followed "[e]very circuit court decision addressing this issue under the MDA." Pet. App. 14a.

Plaintiffs' complaint does not assert a claim for violation of federal requirements R 1-3.[37] Nonetheless, plaintiffs contend that their tort claims would be preserved if they were recast as claims that "seek only to enforce federal standards" (Cross-Pet. Br. 45-46), because they would not then impose any requirements that are "different from, or in addition to," the federal requirements applicable to the Model 4011. The United States agrees that identical state requirements are not "different from, or in addition to," the federal requirements, and further maintains that damages remedies based on such identical standards are not "requirements" at all. U.S. Br. 11-15, 22-28.[38]

[37] Florida law may not even recognize such a claim. For example, under Florida law, it may well be inappropriate to instruct the jury that the doctrine of negligence per se applies, even if an alleged statutory violation typically constitutes negligence. *Underwriters at LaConcorde* v. *Airtech Servs., Inc.*, 493 So. 2d 428, 431 (Fla. 1986) (Boyd, J., concurring in part and dissenting in part). Furthermore, the Florida courts have not resolved definitively whether negligence per se even applies to violations of administrative regulations as well as to violations of statutes. *Id.* at 430. It is even less clear whether negligence per se applies to violations of federal regulations. See, e.g., *Murray* v. *Briggs*, 569 So. 2d 476, 480 (Fla. Dist. Ct. App. 1990) ("[A]lthough several courts seem comfortable with the concept, we are not satisfied that a federal regulation should necessarily control state-law questions of negligence by enlarging common law duties or creating new duties.") (footnote omitted), review denied, 581 So. 2d 165 (Fla. 1991); see also *Cadillac Fairview of Fla., Inc.* v. *Cespedes*, 468 So. 2d 417, 421 (Fla. Dist. Ct. App.) (OSHA violation not dispositive on state-law questions of negligence or products liability), review denied, 479 So. 2d 117 (Fla. 1985).

[38] As the United States notes, an FDA regulation has interpreted the statutory phrase "different from, or in addition to," as excluding state requirements that are "equal to" or "substantially identical" to the applicable federal requirements. U.S. Br. 12-13 (quoting 42 Fed. Reg. at 30,384); accord 21 C.F.R. 808.1(d)(2). The government, however, notably refrains from asking this Court to defer to that agency pronouncement. A state requirement

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In pressing the latter argument, the government purports to rely on the FDA's "consistent[], and reasonabl[e], constru[ction of] the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10.

The Court should reject all of these arguments. Plaintiffs' interpretation is contrary to the language and structure of the preemption clause. Their interpretation also is wrong, because it would undermine the congressional intent to establish uniform device requirements. In addition, the government is mistaken in arguing that tort-law damages remedies do not qualify as "requirements." In fact, the FDA on several occasions has indicated that state enforcement provisions and remedies *are* "requirements." Accordingly, plaintiffs' damages claims are preempted even if they were recast as based on federal standards.

A. State Requirements Are "In Addition To" Federal Requirements Even When They Embody Identical Standards

Plaintiffs and the government do not make *any* effort to explain how the phrase "different from, or in addition to," can be read to exclude state requirements that are identical to federal requirements. This is not surprising, because the statutory language is not susceptible to the interpretation they advocate—for at least four reasons.

1. Plaintiffs' interpretation treats the statute as if it refers only to state requirements that are "different" and thus fails to give *any* independent meaning to the phrase "in addition to." But Congress did not limit preemption to state requirements that are "different from" federal requirements; it said that requirements that are either "different from, *or in addition to*," federal requirements are preempted. Each word of a statute must

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that is only "substantially identical" to a federal requirement would be—almost by definition—"different from" the federal requirement and therefore plainly preempted.

be afforded some meaning. See, e.g., *United States Department of Treasury* v. *Fabe*, 113 S. Ct. 2202, 2210 n.6 (1993). That basic tenet of statutory construction alone defeats plaintiffs' argument.

As a matter of ordinary usage, a state requirement that is identical in content to a federal requirement could fairly be described as an "addition[al]" requirement (just as a second coat of paint of the same color "adds to" or is "in addition to" the first coat). Indeed, this is the *most natural* reading of the phrase "in addition to." State requirements "add to" federal requirements by imposing another set of substantive rules, even if the content of both sets of rules is the same. The manufacturer's obligation to comply with an identical state requirement is completely independent of any federal-law compliance requirement. And again, the phrase "in addition to" must include *some* requirements that are identical, because that is all that remains after "different" state requirements are preempted. Thus, the language of Section 360k(a) does not preserve state requirements that are identical to federal requirements.

Furthermore, plaintiffs allege that Florida law imposes on Medtronic the *requirement* to pay compensatory damages for a violation of standards identical to the federal standards—a requirement that federal law does not impose.[39] Thus, the phrase "in addition to" encompasses that requirement as well as any state requirement that is identical to the federal requirements.

2. Congress knows how to write a preemption provision preserving identical state requirements, as it did in two other sections of the FDCA. See 21 U.S.C. 343-1(a) (preempting state

[39] Under the FDCA, the federal government's potential remedies include seizures, injunctions, civil penalties, criminal penalties, cease and desist orders, and orders requiring recalls, notification of hazards and device repairs, replacements, or refunds. 21 U.S.C. 331-334, 360h. Plaintiffs' demand for payment of damages under state law is a substantial additional requirement different from, and in addition to, these FDCA remedies.

food requirements "not identical to" federal requirements); *id.* § 360ss (preempting state radiation standards "not identical to" federal standards). Similarly, Congress has stated explicitly in other statutes' preemption provisions that identical state requirements are not preempted. See, e.g., 15 U.S.C. 1476(a), 2075(a), 2617(a)(2)(B); 49 U.S.C. 30103(b); 46 U.S.C. 4306. See generally MDMA Br. 19 n.25 (quoting similar statutes). Yet Congress obviously did not use such language in drafting the broader preemption provision of the MDA.

In fact, during its consideration of the MDA, Congress *rejected* two versions of the preemption provision that would have exempted identical state requirements. Both an early House bill and the Senate bill that was sent to conference (where its version of the preemption provision was rejected) provided that state requirements were preempted unless they were "identical to" certain federal requirements. H.R. 9984, 93d Cong., 1st Sess. (1973); 121 Cong. Rec. S 6161 (daily ed. Apr. 17, 1975). Congress, however, significantly broadened this language in the final bill to encompass state requirements that are "different from, or in addition to," federal requirements. If Congress had meant to say that it preserved state law "identical to" federal law, it easily could have—and would have—done so.

3. Other preemption provisions in the U.S. Code confirm that, when Congress directs the preemption of state requirements that are "in addition to" or "different from" federal requirements, it does not intend to spare "identical" state requirements. Indeed, the phrase sweeps so broadly that is has been used to mandate preemption of an entire field of state regulation. See 7 U.S.C. 4817 (in statute "intended to occupy the field of—(1) promotion and consumer education involving pork and pork products; and (2) obtaining funds therefor from pork producers," stating that, during certain periods and with certain exceptions, "[t]he regulation of such activity * * * that is *in addition to or different from* this chapter may not be imposed by a State") (emphasis added); see also *Lynbrook Farms* v. *Smithkline Beecham Corp.*, No. 95-2051, slip op. 2, 6-7, 17 (7th

Cir. Mar. 21, 1996) (affirming field preemption under agency regulation prohibiting state "requirements . . . different from, or in addition to, those imposed by USDA" even though "the conclusion we reach today leaves Lynbrook and similar plaintiffs no remedy for the injuries and losses they have suffered"). In addition, other statutes preempt "additional" or "different" state requirements but provide an explicit *exception* preserving state requirements that are consistent with federal law. See, e.g., 21 U.S.C. 678; *id.* § 1052(a), (b). Congress, of course, made no such exception in the FDCA preemption provision.

4. As plaintiffs acknowledge, there is no express or implied private right of action for violation of the FDCA or related regulations. Cross-Pet. Br. 30-31 (citing *Bailey* v. *Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995)); see also 21 U.S.C. 337 ("[P]roceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Congress's omission of a private right of action reflects an intent to reserve enforcement of federal requirements exclusively to the federal government. It is most unlikely that Congress intended to foreclose private enforcement of federal norms but to allow states to permit such private enforcement of identical norms under state law. See MDMA Br. 23-26. For that reason as well, the Court should reject plaintiffs' interpretation.[40]

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[40] Cf. *Merrell Dow Pharmaceuticals Inc.* v. *Thompson*, 478 U.S. 804, 812 n.10 (1986) ("When we conclude that Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless.' "); *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.) (claim for FDCA violation barred because no private right of action exists), cert. denied, 115 S. Ct. 429 (1994).

B. Plaintiffs' Construction of the Statute is Inconsistent With the Congressional Intent to Establish Uniform Requirements

Although plaintiffs theorize that it would be possible to cast common law claims so that they necessarily would establish requirements identical to federal standards, their theory departs from reality. The inability of courts to ensure consistency in practice would create an irregular pattern of liability exposure for device manufacturers, undermining the congressional intent to impose uniform requirements. The danger that such a regime would frustrate the fundamental objective of the preemption provision reinforces the conclusion that, if Congress had intended to preserve "identical" state requirements from preemption, it would have said so in the text of the statute.

If the FDCA preserved claims for violation of state standards that are identical to federal requirements, differing *interpretations* of federal requirements inevitably would arise as these claims were adjudicated. There is no reason to expect that a lay jury or state judge interpreting a federal requirement necessarily would reach the same construction as the FDA, particularly in cases such as this one, in which there has been no suggestion that the agency believes its requirements have been violated. The risk that state juries and judges would interpret identical requirements inconsistently or "different[ly]" from the FDA is greatly heightened, moreover, because many federal requirements are cast in relatively broad terms.[41]

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[41] As administered by the FDA, the federal enforcement scheme established by the statute substantially ensures that the federal government will take uniform positions in litigation involving interpretations of the FDCA and related regulations. The FDA General Counsel's Office must approve all enforcement actions for legal sufficiency (Arthur N. Levine, FDA Enforcement Manual at 71 (Apr. 1994)), and those actions filed in federal court also are coordinated through the Civil Division of the Department of

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These varying interpretations would render the state requirements "different" from the federal requirements, and therefore preempted. This Court has made clear that preemption depends upon "the relationship between state and federal laws as they are interpreted and applied, not merely as they are written." *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 526 (1977). The FDA also has acknowledged that a state's *application* of a requirement determines whether it is different from, or in addition to, the federal requirement under the FDCA preemption provision. See, e.g., 43 Fed. Reg. 18,661, 18,663 (May 2, 1978); 21 C.F.R. 808.20(c)(1) (requiring submission of judicial and administrative interpretations in petition for exemption from preemption). As a result, claims premised upon these differing interpretations could not survive preemption. Cf. *Merrell Dow*, 478 U.S. at 815 ("[t]o the extent that petitioner is arguing that state use and interpretation of the FDCA pose a threat to the order and stability of the FDCA regime, petitioner should be arguing * * * that the FDCA pre-empts state-court jurisdiction" over state common law claims for FDCA violations). The irrational pattern of liability exposure that would emerge from varying case-by-case interpretations of the federal requirements is so inconsistent with the expressed congressional desire to promote uniformity that it is reasonable

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Justice. See 28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(9), (10). This coordination helps assure that judicial interpretations of the FDCA and related regulations are uniform. In contrast, permitting private plaintiffs to adopt and assert their own interpretations of the federal requirements in product liability litigation without any nationwide coordination by, or oversight from, the federal experts would inevitably lead to imposition of differing standards. Indeed, as the United States acknowledges, private plaintiffs could assert that a manufacturer has violated FDCA requirements *even if the FDA disagrees*. U.S. Br. 26.

to conclude that if Congress had intended to preserve "identical" state requirements, it would have said so explicitly.[42]

Furthermore, the extraordinary practical difficulties of such a regime confirm that plaintiffs' construction of the statute is wrong. If a state jury determined that a device's labeling was "false and misleading" under the "federal" standard because it omitted some information, a manufacturer would be obliged to change the labeling at least in that state or else risk additional adverse verdicts (possibly even punitive damages awards). But to effectuate such a change the manufacturer would need clearance from the FDA. The FDA, however, might withhold clearance on the ground that the existing labeling is *not* false and misleading, or because the new information would dilute other warnings that the agency deems more important. Worse yet, it is conceivable that *many* states, acting through common law tort actions purportedly applying general federal requirements to specific devices as part of the "identical" law of each state, would impose *irreconcilable* requirements on a manufacturer. And there is no guarantee that the FDA would decide which conflicting interpretation of federal standards is correct. This pattern of conflicting standards would be wholly inconsistent with the congressional intent to promote uniformity.

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[42] The Solicitor General suggests that state juries could simply be instructed to determine whether a device's labeling is "false and misleading" or bears "adequate directions for use." U.S. Br. 27. Making a virtue of necessity, the Solicitor General points out that he "cannot say" that a jury's determination of such issues "would of necessity rest on any common-law duty of care that is 'different from, or in addition to,' (21 U.S.C. 360k(a)(1)) the Act's labeling provisions." U.S. Br. 28. That is precisely our point. Under the regime advocated by the government, preemption could be determined, if at all, only after the jury's verdict in a post-trial motion—an odd result indeed (as well as a colossal waste of judicial resouces).

C. The Obligation To Pay Damages Is A "Requirement"

Evidently recognizing that plaintiffs' claims, if successful, would require Medtronic to do something "different from, or in addition to," what federal law requires, the Solicitor General contends that an obligation to pay damages rooted in state tort law is not a "requirement" within the meaning of Section 360k(a). He further suggests the FDA has "consistently, and reasonably, construed the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10. Those assertions are wrong.

1. There is no basis *in the text of the statute* for distinguishing between an obligation to conform a medical device's design, labeling, or manufacture to state-law standards and an obligation to pay damages for the violation of such a standard. Both are "requirements." Indeed, two sections of the FDCA refer to 21 U.S.C. 360h—which is entitled "Notification And Other Remedies" and is devoted exclusively to remedies—as prescribing "requirement[s]." 21 U.S.C. 352(t), 331(q)(1). As the Solicitor General elsewhere concedes (U.S. Br. 24 n.19), something that is described as a "requirement" elsewhere in the FDCA should be regarded as a "requirement" for purposes of the preemption provision. It follows that remedies *are* "requirements."

The distinction drawn by the government is particularly untenable in light of the authority of state attorneys general to obtain equitable remedies for violations of common law duties. See, e.g., *Mayor of Georgetown* v. *Alexandria Canal Co.*, 37 U.S. (12 Pet.) 91, 98 (1838); *State* v. *First Nat'l Bank*, 600 P.2d 406, 421 (Alaska 1982). Under the government's reading, a state could enjoin distribution of a device under its common law for violating a federal requirement, even though the FDA had decided both that the same violation is trivial *and* that continued distribution of the device is in the public interest. See 21 U.S.C. 336 ("Nothing in [the FDCA] shall be construed as requiring the

Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of [the FDCA] whenever he believes that the public interest will be adequately served by a suitable written notice or warning."). There is no reason to attribute to Congress a design that would produce such an absurd result.

2. The United States can draw no support from previous statements of the FDA relating to Section 360k(a). Contrary to the Solicitor General's submission, the FDA has *not* previously "construed the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10. That novel interpretation is nothing more than an invention of the government's litigators in this case. Indeed, several of the agency pronouncements cited by the government conclusively establish that the agency has recognized that state "remedies" *are* a kind of "requirement" within the meaning of Section 360k(a).

The Solicitor General points to three FDA statements. U.S. Br. 12-13. First, he notes that the FDA has interpreted Section 360k(a) not to preempt *identical* or *substantially identical* state requirements. U.S. Br. 12. That is true but irrelevant, because this interpretation rests not on the word "requirement" but rather on the phrase "different from, or in addition to." 43 Fed. Reg. at 18,663; 42 Fed. Reg. 30,383, 303,84 (June 14, 1977).

Second, the Solicitor General notes that the FDA has said that Section 360k(a)

> does not preempt those State or local *requirements respecting general enforcement*, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments.

21 C.F.R. 808.1(d)(6)(i) (emphasis added), cited in U.S. Br. 13. According to the Solicitor General, this passage demonstrates that the FDA has long recognized the distinction between remedies and substantive requirements. That is doubly incorrect.

The quoted passage, by referring to state enforcement provisions as "requirements," flatly *refutes* the government's assertion (and shows that the FDA *does* regard enforcement provisions as "requirements"). In addition, the FDA's *reason* for concluding that state enforcement provisions are preserved was its former view—which rested on language in the preemption clause *other than* the word "requirement"—that state requirements of "general applicability" are not preempted (a view that the United States elsewhere rejects in its brief). See 42 Fed. Reg. at 30,384; 43 Fed. Reg. at 18,663.

For exactly the same reasons, the 1984 FDA advisory opinion cited by the government (U.S. Br. 13; see Cross-Pet. Br. 12a-13a) actually refutes the agency interpretation claimed in the government's brief. According to the Solicitor General, that FDA letter "made clear that the state 'enforcement provisions' that [the FDA] considers not to constitute 'requirement[s]' include *judicial* remedies sought by private parties to enforce state substantive requirements." U.S. Br. 13. In fact, the letter asserts that remedies *are* requirements, stating that Congress did not intend preemption of "State or local *requirements* respecting general enforcement, *including available legal remedies*, or State or local statutes that only incidentally apply to devices." Cross-Pet. Br. 13a (emphasis added). The agency's reason for reaching this conclusion was its former (and now repudiated) view that requirements of general applicability are not preempted. *Ibid.*

In short, far from "consistently, and reasonably, construe[ing] the term 'requirement' to refer to substantive, but not remedial, provisions" (U.S. Br. 9-10), the FDA has on several occasions indicated that "requirements" include state remedies and enforcement provisions. This Court also should conclude that remedies are state requirements subject to FDCA preemption.

CONCLUSION

The Court should affirm in part the judgment of the Eleventh Circuit and hold that the Federal Food, Drug, and Cosmetic Act preempts plaintiffs' negligence and strict liability claims for failure to warn and defective manufacture regarding the Medtronic Model 4011 cardiac pacemaker lead.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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27 pp

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

I. THE REQUIREMENTS OF THE 510(K) PROCESS HAVE PREEMPTIVE EFFECT 5

II. PLAINTIFFS' CLAIMS WOULD ESTABLISH STATE REQUIREMENTS WITHIN THE MEANING OF THE PREEMPTION PROVISION 7

A. Plaintiffs' Claims Would Establish "Requirements" 7

B. Plaintiffs' Claims Would Impose Requirements Established by a "State or Political Subdivision" 8

III. PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD ESTABLISH STATE REQUIREMENTS "DIFFERENT FROM, OR IN ADDITION TO," THE 510(K) REQUIREMENTS 9

A. The 510(k) Requirements Regulate Device Design 9

B. Plaintiffs' Claims are Preempted Because They Would Expose Medtronic to Liability for Marketing a Federally Authorized Design 10

C. Plaintiffs' Claims are Preempted Because They Would Require Medtronic to Change the Design of the Model 4011 13

IV. PREEMPTION IS CONSISTENT WITH THE STATUTORY SCHEME 15

CONCLUSION 19

TABLE OF AUTHORITIES

CASES Page

American Airlines, Inc. v. *Wolens*, 115 S. Ct. 817 (1995) 7

Barnett Bank v. *Nelson*, No. 94-1837 (Mar. 26, 1996) 12

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) 7,8,13,14

CSX Transportation, Inc. v. *Easterwood*, 507 U.S. 658 (1993) 8,9,14

Erie Railroad v. *Thompkins*, 304 U.S. 64 (1938) 8

Fidelity Federal Savings & Loan Ass'n v. *De la Cuesta*, 458 U.S. 141 (1982) 12

Guaranty Trust Co. of New York v. *York*, 326 U.S. 99 (1945) 9

Public Employees Retirement System of Ohio v. *Betts*, 492 U.S. 158 (1989) 6

San Diego Building Trades Council v. *Garmon*, 359 U.S. 236 (1959) 4

Silkwood v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984) 16,17

United States v. *An Article of Device*, 607 F. Supp. 990 (W.D. Mich. 1985) 12

STATUTES

Atomic Energy Act of 1954 17

Price-Anderson Act 17

Pub. L. No. 94-295, sec. 10, 90 Stat. 539 (1976) 17

Public Health Cigarette Smoking Act of 1969 7

21 U.S.C. 321(n) 1a

TABLE OF AUTHORITIES continued

Page

21 U.S.C. 331 ..... 1a

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21 U.S.C. 334 ..... 1a

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21 U.S.C. 351(f)(1)(B) (1982) 12

21 U.S.C. 351(h) 1a

21 U.S.C. 352 ..... 1a

21 U.S.C. 352(o) 1a

21 U.S.C. 352(t) 1a

21 U.S.C. 360(j) 1a

21 U.S.C. 360(k) ..... *passim*

21 U.S.C. 360c(d)(2)(A) 5

21 U.S.C. 360c(i)(2) 20

21 U.S.C. 360f(a)(2) 1a

21 U.S.C. 360h(a) 1a

21 U.S.C. 360h(b) 1a

21 U.S.C. 360i 1a

21 U.S.C. 360j(a) 5

21 U.S.C. 360j(f) 1a

21 U.S.C. 360k 17

21 U.S.C. 360k(a) 1,6,7,9,15

21 U.S.C. 360k(b) 14,15

21 U.S.C. 374 ..... 1a

42 U.S.C. 2018 17

42 U.S.C. 2021(b) 17

42 U.S.C. 2021(k) 17

TABLE OF AUTHORITIES continued

Page

REGULATIONS

21 C.F.R. Pt. 1 ..... 1a
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21 C.F.R. Pt. 803 ..... 1a
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21 C.F.R. 807.81(a)(3)(i) 13
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21 C.F.R. 884.5360(d) 16
41 Fed. Reg. 37,458 (Sept. 3, 1976) 12
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OTHER AUTHORITIES

121 Cong. Rec. S 6161 (daily ed. Apr. 17, 1975) 8
H.R. Rep. No. 853,
94th Cong., 2d Sess. (1976) 1,4,16,17,18
S. Rep. No. 513, 101st Cong., 2d Sess. (1990) 12

REPLY BRIEF FOR PETITIONER MEDTRONIC, INC.

Respondents' brief has two noteworthy features. It expends most of its energy debating an issue that has nothing to do with the language of the statute being construed: the relationship between 510(k) clearance and device safety or effectiveness. It also mischaracterizes Medtronic's position at every turn, proceeding to knock down straw men it creates without ever refuting the positions Medtronic *actually* has taken in this Court. If the Court reads the statute and Medtronic's briefs *as written*, and is not led astray by plaintiffs' diversionary tactics, it will conclude that the design defect claims in this case are preempted.

The statutory language is completely unaccommodating to plaintiffs' position. It states (21 U.S.C. 360k(a) (emphasis added)):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, *any requirement applicable under this chapter to the device*, and
>
> (2) which *relates to* the safety or effectiveness of the device *or* to any *other* matter included in a requirement applicable to the device under this chapter.

The statute states unambiguously that the federal requirement need not relate to safety or effectiveness in order to have preemptive effect; it need only be "applicable to the device." Even the *state* requirement need not relate to safety or effectiveness; it is preempted if it relates to any other matter included in an applicable federal requirement and is different from, or in addition to, that requirement. The legislative history therefore is entirely accurate in describing Section 360k(a) as a "general prohibition on non-Federal regulation." H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). Medtronic has made these

points before (see Pet. Br. 18-19, 30-31; Cross-Resp. Br. 1, 19-20, 25-27), yet plaintiffs steadfastly refuse to admit that *any* federal requirement "applicable * * * to the device" is preemptive. Instead, they debate at length whether "the 510(k) process involves a safety and effectiveness determination." Resp. Br. 29-30. But that issue is *irrelevant*; a federal requirement need only be "applicable * * * to the device" to have preemptive effect, and the 510(k) process indisputably is.[1]

In an apparent effort to persuade the Court that it matters whether the 510(k) process entails a safety and effectiveness "determination"—and that the Court should address other issues not raised by the statutory text—plaintiffs ascribe to Medtronic a host of positions that it never took.

Medtronic *never* argued that "the FDA's determination is a finding of the safety and effectiveness of the device's design." Resp. Br. 25; see also *id.* at 29-30. Such an argument would be insupportable, but it also is completely unnecessary to Medtronic's position, which is that the 510(k) process is preemptive because it imposes "requirement[s] applicable * * * to the device."[2]

Medtronic *never* attempted to show "some kind of federal *approval* for the design" of its device. Resp. Br. 24 (emphasis

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[1] Plaintiffs seriously understate the degree to which the 510(k) process and other federal requirements protect the public against unsafe or ineffective medical devices. See pp. 18-19, *infra*; Pet. Br. 5-10, 18-30. We join issue with plaintiffs on this point because the Court should not be misled (and because the Eleventh Circuit thought it important, see Pet. App. 25a-27a), but the Court need not resolve the debate; it need only conclude that the 510(k) requirements are "applicable * * * to the device" and then address the other statutory criteria, which apply to the *state* requirement. See Pet. Br. 36.

[2] The 510(k) process unquestionably *relates to* safety and effectiveness, although it need not do so in order to be preemptive. See Pet. Br. 18-30. But claiming, as Medtronic does, a relationship to safety and effectiveness is not the same as claiming that the process entails a *finding* of safety and effectiveness.

added). Medtronic showed federal *authorization* of that design, Pet. Br. 19-21, 27-28, but never claimed that the FDA would regard that authorization as an "*approval*." See *id.* at 21 n.9. And Medtronic also explained that preemption turns on applicable federal *requirements* rather than the terminology used to describe clearance for marketing. See *id.*

Medtronic *never* "claim[ed] that Congress sought to enshrine the substantial equivalence process as a permanent substitute for premarket approval for certain Class III devices." Resp. Br. 27; see also *id.* at 28. Medtronic instead explained that PMAs have not yet been required for pacemaker leads (and may never be required because they may be reclassified within the time limits Congress set in 1990 (Pet. Br. 29-30)); but none of this has anything to do with the statutory criterion, because 510(k) requirements, like PMA requirements, plainly are "applicable * * * to the device."

Medtronic *never* argued, in this Court or in the court below, that "the FDA's authority to order *labeling* changes to a marketed device would be 'different from, or in addition to' a claim regarding a device's *design*." Resp. Br. 17 (citation omitted). Neither the cited page from Medtronic's opening brief in this Court (Pet. Br. 44) nor the cited page from the opinion below (Pet. App. 28a) supports plaintiffs' assertion, and plaintiffs elsewhere recognize that Medtronic acknowledges the need for "some subject-matter congruence between the federal law that is said to preempt and the state law that is said to be preempted." Resp. Br. 21-22. Showing such a relationship is the whole point of the lengthy portions of Medtronic's prior briefs describing federal requirements applicable specifically to design, labeling, and manufacturing—the three subjects of plaintiffs' claims. See Pet. Br. 18-30; Cross-Resp. Br. 21-24, 31-34.

Medtronic *never* argued that "*all* state laws regarding medical devices" are preempted. Resp. Br. 19; see also *id.* at 16. States may retain considerable freedom, for example, to regulate medical device pricing or to apply certain aspects of state

contract law to medical devices. See Cross-Resp. Br. 18 n.18. The preemption of state tort law surely *is* broad, but that is the inevitable consequence of coupling a "general prohibition on non-Federal regulation" (H.R. Rep. No. 853, at 45) with this Court's longstanding recognition that "regulation can be as effectively exerted through an award of damages as through some form of preventive relief" (*San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)).

Medtronic *never* argued that "Congress' purpose" in the MDA was "simply to encourage the marketing of medical devices." Resp. Br. 38. Instead, as plaintiffs elsewhere concede (see *id.* at 37), Medtronic consistently has said that the MDA created a *balanced* regulatory scheme that *both* encourages device innovation and availability *and* protects consumers from unsafe and ineffective devices. It is plaintiffs, not Medtronic, who only discuss one statutory purpose. See Cross-Pet. Br. 3, 28-29; Resp. Br. 38-39. Plaintiffs simply are wrong, not only because the legislative history recognizes other purposes, but also because there would be no rationale whatever for the enactment of the preemption clause *itself* if plaintiffs' view of the statute were correct.

Finally, Medtronic *never* made the free-standing policy arguments that plaintiffs attack at pages 12-15 of their second brief, and certainly never argued that "whenever Congress sought to regulate a particular product and preempt state positive law, all common-law actions that provided a remedy for injuries caused by that product would be swept away." Resp. Br. 14. Medtronic argues that plaintiffs' common law claims are preempted because *Congress said so* in an express preemption clause, not because common law claims are preempted whenever Congress regulates a product.

One other pervasive misimpression created by plaintiffs deserves comment before we address each statutory criterion in turn. Plaintiffs depict an imaginary world in which there are "devices wholly unregulated by federal law" (Resp. Br. 37 n.11,

24) and devices for which "federal regulation is only a remote possibility, not a reality" (*id.* at 36). Those flights of rhetoric have no basis in fact. *Every* medical device, including devices introduced before 1976, is regulated under the MDA. See App., *infra*, 1a. The *degree* of regulation may vary depending upon the classification and intended use of the device, with PMA-approved devices more heavily regulated than 510(k) devices, Class III prescription devices such as the Model 4011 more heavily regulated than other 510(k) devices (see HIMA Br. 18-19), and 510(k) devices in turn more heavily regulated than pre-MDA devices (see App. 1a). But completely unregulated devices are as fictional as unicorns. Furthermore, if unregulated medical devices *did* exist, there would be no preemption of state law, because there would be no federal requirement "applicable to the device"; Medtronic never has contended otherwise. In any event, the device in the case before the Court is the Medtronic Model 4011 pacemaker lead, which is heavily regulated, as Medtronic demonstrated in its first two briefs. As we again show, plaintiffs' claims that the lead was defectively designed satisfy every statutory criterion for preemption.

I. THE REQUIREMENTS OF THE 510(K) PROCESS HAVE PREEMPTIVE EFFECT

Although they argue at length that the 510(k) requirements are not preemptive, plaintiffs largely ignore the statutory language stating that *any* FDCA requirement "applicable to the device" may preempt state law. Plaintiffs refuse to discuss two sections of the FDCA cited in Medtronic's opening brief, which characterize Section 510 as imposing "requirements" that are "appl[icable] to the device" and thereby confirm that the 510(k) requirements are preemptive. See Pet. Br. 31-32; 21 U.S.C. 360c(d)(2)(A), 360j(a); cf. U.S. Br. 24 n.19 (conceding that the GMP regulations are preemptive precisely because other sections of the FDCA describe them as "requirements"). Instead, plaintiffs merely reiterate their assertion that federal requirements are not preemptive unless they are device-specific, because the statute refers to requirements "applicable to *the*

device." Although Medtronic will not repeat its previous responses to plaintiffs' strained construction (see Pet. Br. 33-36; Cross-Resp. Br. 25-27), three additional points are worth noting.

First, plaintiffs misread the preemption provision by construing a reference to "*the* device" as a statement that only device-specific federal requirements are preemptive. The preemption provision prohibits defined state requirements "with respect to *a* device" if there is a federal requirement "applicable * * * to *the* device." 21 U.S.C. 360k(a) (emphasis added). This use of the definite article does nothing more than clarify, sensibly, that a federal requirement must apply to the *same* device as a state requirement it preempts.

Second, plaintiffs rely for their interpretation on an agency regulation (21 C.F.R. 808.1(d)) and, incredibly, argue that this Court should accord it "substantial deference" (Resp. Br. 19) even though the FDA, through the Solicitor General, has abandoned the regulation and agreed with Medtronic that the statute does not restrict preemptive federal requirements to those that are device-specific. Cross-Resp. Br. 26-27; U.S. Br. 24 n.19, 25 n.20. Because even the FDA agrees that the statute is inconsistent with plaintiffs' construction of the regulation, there is no basis for deference. Cf. *Public Employees Retirement Sys. of Ohio* v. *Betts*, 492 U.S. 158, 171 (1989).[3]

Third, plaintiffs briefly refer to the Solicitor General's argument that the design *specifications* for the Model 4011 are not requirements applicable to the device "under *th[e Act]*," because they originated in voluntary decisions of the

[3] Plaintiffs are incorrect even in their interpretation of the regulation. As the Eleventh Circuit correctly concluded (in line with the explicit or implicit rulings of eight other courts of appeals), the language of the FDA's regulation "does not suggest that the requirements themselves must mention the particular device in question" to be preemptive. Pet. App. 19a. This construction is consistent with another section of the same regulation stating that the GMP regulations (which apply to thousands of devices) may preempt state law. See 21 C.F.R. 808.1(d)(6)(i).

manufacturer. Resp. Br. 23; U.S. Br. 20. As Medtronic explained in its first brief, however, once a device's design is submitted to and authorized by the FDA, federal regulations prohibit *changes* that could significantly affect safety or effectiveness without agency clearance; what *starts out* as a voluntary decision thus becomes a binding and limiting federal requirement.[4] The 510(k) requirements that regulate device design unquestionably are "applicable under [the FDCA] to the device," and they therefore are preemptive.

II. PLAINTIFFS' CLAIMS WOULD ESTABLISH STATE REQUIREMENTS WITHIN THE MEANING OF THE PREEMPTION PROVISION

A. Plaintiffs' Claims Would Establish "Requirements"

Medtronic explained in its first two briefs why the language of the statute, informed by this Court's decision in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), shows that plaintiffs' claims would establish "requirements" subject to preemption. Pet. Br. 36-39; Cross-Resp. Br. 9-12; see also U.S. Br. 15-19 (common law duties are state "requirements" under Section 360k(a)). One new point raised by plaintiffs deserves a short response. According to plaintiffs, the holding in *Cipollone* depends fundamentally upon differences in language between the Public Health Cigarette Smoking Act of 1969 and a predecessor statute with a preemption provision limited to positive law. Resp. Br. 7-9. This argument is absurd, because it

[4] The government also mischaracterizes the Model 4011's design specifications by implying that there are no federal requirements affecting those specifications and comparing them to the voluntary contract terms at issue in *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817 (1995). U.S. Br. 20-21. Although the Model 4011's specifications did not originate from the FDA, they are not "privately ordered obligations" analogous to the terms of a contract. Cf. *id.* at 824. In order to pursue marketing under the 510(k) process, Medtronic had to design the Model 4011 in accordance with the statutory requirement that it must be substantially equivalent to a preamendment device. See Pet. Br. 19-27.

suggests that a statute with the same language as the 1969 Act (such as the FDCA) would not preempt common law claims in the *absence* of a predecessor statute. There is no justification for demanding a prior enactment as a prerequisite for interpreting the plain language of the statute as extending to common law claims.[5]

B. Plaintiffs' Claims Would Impose Requirements Established by a "State or Political Subdivision"

As is typical throughout their brief, plaintiffs discuss the wrong issue when they assert that "Medtronic must demonstrate that *a jury award* in a medical device case is issued by a 'State or political subdivision of a State.'" Resp. Br. 10 (emphasis added). The question is not whether a *jury award* establishes or continues in effect state requirements, but whether *state common law* establishes or continues in effect requirements that a judge or jury enforces by awarding relief in a tort action involving a medical device. And that is not a difficult question; this Court answered it definitively nearly sixty years ago.

"At least since *Erie R. Co.* v. *Tompkins*, 304 U.S. 64 (1938), [the Court has] recognized the phrase 'state law' to include common law as well as statutes and regulations." *Cipollone*, 505 U.S. at 522. Thus, in *Cipollone* and again in *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658 (1993), the Court rejected plaintiffs' assertion that the State has not acted when judges and juries resolve common law claims. In *Easterwood*, the Court affirmed preemption of common law claims under a Federal Railroad Safety Act provision that bars "[a] State" from "adopt[ing] or

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[5] Plaintiffs also ignore the legislative history of the FDCA preemption provision, which involved changes in statutory language directly analogous to the changes between the two statutes at issue in *Cipollone*. The Senate bill that preceded the MDA limited preemption to positive state law, prohibiting "any provision of a standard or regulation which prescribes any requirements" regarding certain enumerated subjects. 121 Cong. Rec. S 6161- S 6162 (daily ed. Apr. 17, 1975). The final bill drafted by the Conference Committee, of course, broadened the language and used the term "requirement."

continu[ing] in force" certain railroad safety standards. 507 U.S. at 662 n.2, 673-76. This language is in relevant respects indistinguishable from the FDCA.

Furthermore, plaintiffs' argument that there can be no preemption in federal diversity cases does not withstand scrutiny. See Resp. Br. 10-11. That argument is flatly foreclosed by *Easterwood*, in which this Court affirmed preemption under the statutory language quoted above in a federal diversity suit. See 507 U.S. at 661. Federal judges and juries sitting in diversity, no less than state judges and juries, apply "requirement[s]" "establish[ed] or continue[d] in effect" *by the State*. See *Guaranty Trust Co. of New York* v. *York*, 326 U.S. 99, 108-09 (1945) (federal court sitting in diversity is, "in effect, only another court of the State"). Plaintiffs' argument would lead to the absurd conclusion that federal courts may apply otherwise-preempted state common law but state courts may not. That reading of the preemption provision is neither sensible nor consistent with its language.

III. PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD ESTABLISH STATE REQUIREMENTS "DIFFERENT FROM, OR IN ADDITION TO," THE 510(K) REQUIREMENTS

A. The 510(k) Requirements Regulate Device Design

Plaintiffs' argument hinges on the assertion that the 510(k) process "does not impose requirements that relate in any way to device design." Resp. Br. 6; see also *id.* at 15-24. They further argue that, if there is no federal requirement relating to device design, any state requirement established through their design claims could not properly be characterized as "different from, or in addition to," a federal requirement. *Id.* at 24. But plaintiffs *completely ignore* the sections of Medtronic's opening brief explaining that a design is marketable under the 510(k) process only if it is substantially equivalent to a preamendment device and that manufacturers must submit design information for FDA review (Pet. Br. 22-23); plaintiffs also refuse to acknowledge

that 510(k) premarket clearance depends fundamentally upon the FDA's comparison of the designs of the device under review and the predicate device (*id.* at 23-25).

What plaintiffs are really arguing is that there can be no federal requirements relating to device design unless those requirements *specify* the design. See Resp. Br. 22. As Medtronic explained in its opening brief, however, there is no basis in the statutory language for limiting preemption to circumstances in which there are particular federal design specifications. Pet. Br. 32-36. And, because the 510(k) requirements plainly regulate device design, there is more than adequate basis for determining that plaintiffs' design claims would establish state requirements that are "different" or "addition[al]."

B. Plaintiffs' Claims Are Preempted Because They Would Expose Medtronic to Liability for Marketing a Federally Authorized Design

Medtronic's opening brief explained that plaintiffs' claims would establish state requirements that are *by definition* "different from, or in addition to," federal requirements, because their premise is that the design authorized under the 510(k) requirements violates common law duties. Pet. Br. 44-46. Implicitly recognizing that state requirements *are* preempted if they challenge a federally authorized design, plaintiffs strain to assemble an argument from law review commentaries that 510(k) clearance is not an authorization to market at all. See Resp. Br. 24-25 & n.8. This argument completely mischaracterizes the 510(k) process.

Although plaintiffs note correctly that one purpose of the 510(k) process is to notify the FDA that a company wishes to market a device, they incorrectly assert that the FDA does not need to determine substantial equivalence before marketing may proceed. Resp. Br. 24. From the time the 510(k) process was established, the Agency has made clear that "[t]he requirements of section 510(k) of the act are intended not only to notify FDA that a device is about to be marketed but *primarily* to enable

FDA to determine whether the device is substantially equivalent to one already in commercial distribution." 42 Fed. Reg. 42,520, 42,523 (Aug. 23, 1977) (preamble to 510(k) regulation) (emphasis added); see also *id.* at 42,524 ("[S]ection 510(k) of the act is more than a notification provision."). In addition, since before the 1990 Amendments, the FDA has acted to bar marketing by *rescinding* 510(k) clearance (Pet. Br. 21), yet plaintiffs do not (and cannot) explain how this control over market access could derive from a simple "notification."

As Medtronic explained in its opening brief, the statute bars marketing if the manufacturer has not filed a 510(k) submission, or if a submission is filed but the FDA determines that the device is not substantially equivalent to a preamendment device. See Pet. Br. 19-20. The statute also explicitly bars marketing for ninety days after filing of the 510(k) submission unless the FDA grants clearance sooner. *Id.* at 20. And the FDA *did* grant clearance for the Model 4011 before this ninety-day period ended, authorizing immediate marketing in a letter that stated "[y]ou *may*, therefore, market your device" and conditioning the clearance upon compliance with "the general controls provisions of the Federal Food, Drug, and Cosmetic Act." R1-37-Exh. A to Exh. 1 (emphasis added), *quoted in* Pet. Br. 20.

Although the FDA *did* determine substantial equivalence for the Model 4011, and *did* authorize marketing, plaintiffs (citing law review articles) assert that these FDA actions were not *required* before marketing could proceed. Resp. Br. 24 & n.8. Although they acknowledge that the submission must "explain[] the basis for [the manufacturer's] claim of substantial equivalence" (Cross-Pet. Br. 35), and debate at length the details of the standards the Agency applies to determine substantial equivalence (*id.* 34-35; Resp. Br. 29-35), plaintiffs assert that Congress established a system in which agency review of the submission is only voluntary.

Plaintiffs' argument is nothing more than an unwarranted and insupportable attack on the FDA's administration of the

statute. In fact, the Agency consistently has interpreted the statute to require it to act on every 510(k) submission. See, e.g., 41 Fed. Reg. 37,458, 37,461 (Sept. 3, 1976); see also 42 Fed. Reg. at 42,524 ("[t]he Commissioner *must* determine" substantial equivalence) (emphasis added). And until the FDA *does* find that a device is substantially equivalent to a preamendment device, marketing is barred without an approved PMA.[6] As a result, even if the FDA had failed to act on a 510(k) submission at the time of the Model 4011's clearance, the statute would *not* have allowed marketing; a manufacturer that marketed under those circumstances would have violated the statutory provisions barring marketing in the absence of a required PMA. See 21 U.S.C. 351(f)(1)(B) (1982).

Finally, plaintiffs' characterization of the 510(k) process leads them to an absurd result. Plaintiffs conclude that the FDCA preserves state law requirements, even if they would "remove[] the Model 4011 from the market entirely," Resp. Br. 28, even though the FDA has authorized marketing of the device's design under federal law.[7] Plaintiffs' rationale is fundamentally inconsistent with a long line of cases (including *Fidelity Fed. Savings & Loan Ass'n* v. *De la Cuesta*, 458 U.S. 141, 155-56 (1982), and the Court's most recent preemption decision, *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996)) holding

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[6] See, e.g., *United States* v. *An Article of Device*, 607 F. Supp. 990, 998 (W.D. Mich. 1985). In the 1990 Amendments, Congress confirmed that manufacturers always have been required to obtain a finding of substantial equivalence before marketing is legal without an approved PMA. S. Rep. No. 513, 101st Cong., 2d Sess. 19 (1990) (1990 amendments confirm that under the original statute, a device "automatically" requires PMA approval "unless the Secretary finds that it is substantially equivalent to a device which is not subject to a premarket approval requirement").

[7] As Medtronic has explained previously, the 510(k) clearance is an authorization to market the proposed *design* as well as the device itself, because the FDA has reviewed and cleared a particular design, which may not be changed, without further agency clearance, in a manner that could significantly affect safety or effectiveness. Pet. Br. 27-28.

that if federal law authorizes particular conduct, state law barring the same conduct is impliedly preempted because it frustrates the congressional purpose. The FDCA express preemption provision mandates even *broader* preemption than does the implied preemption doctrine by invalidating state law if it is "different from, or in addition to," federal requirements, regardless of whether the differences or additions are significant enough to frustrate the congressional purpose. Because plaintiffs' claims, if successful, would require Medtronic to pay damages under state law for marketing a device design authorized by federal law, they are preempted.

C. Plaintiffs' Claims Are Preempted Because They Would Require Medtronic to Change the Design of the Model 4011

The statutory phrase "different from, or in addition to," does not demand a direct conflict between federal and state law as a prerequisite for preemption, yet there is a direct conflict in this case. Although plaintiffs again re-argue points resolved against them in *Cipollone* (Cross-Resp. Br. 9-12) and assert that the requirement to pay damages has no regulatory effect (Resp. Br. 12-14, 36), their claims, if successful, would require Medtronic to redesign its device to avoid future liability, Pet. Br. 44-46. And the requirements of the 510(k) process would bar those changes without further FDA clearance, which might not be obtained. *Id.* at 45 & n.21. The feebleness of plaintiffs' response to this point is quite telling.

First, plaintiffs make the specious argument that the changes demanded by state law could be too insignificant to require FDA clearance. Resp. Br. 35-36. The applicable federal regulation requires 510(k) clearance for *any* change "that could significantly affect * * * safety or effectiveness." 21 C.F.R. 807.81(a)(3)(i). Surely plaintiffs do not mean to suggest that state law would support an award of damages to Mrs. Lohr for a design "defect" with *no* significant effect on safety and effectiveness, yet that is the logic of their position. If plaintiffs'

claims were successful, to avoid future liability for negligence, Medtronic would need to change its design to make it reasonably safe for use in a foreseeable manner; to avoid future strict liability, Medtronic would need to change the design so that it was not unreasonably dangerous to foreseeable users. See Pet. Br. 42. It is absurd to argue that these changes, which focus on the essential safety of the device, "could not" significantly affect safety or effectiveness.

Second, the Court should reject plaintiffs' assertion that preemption could not be determined until the FDA denied clearance for the design changes required by state law. Resp. Br. 36. The 510(k) requirements bar relevant changes *unless and until* the FDA authorizes them. Thus, from the moment Medtronic obtained initial marketing clearance for the Model 4011, the changes plaintiffs' claims demand were prohibited. And although a subsequent FDA clearance for the change theoretically could resolve the conflict, it would be nonsensical to suggest that Congress intended such clearance to "undo" preemption; under these circumstances, the state requirements would still be preempted, because they would be "in addition to" the federal requirement. See Cross-Resp. Br. 38-50. The mechanism Congress placed in the statute to "undo" preemption is the *prospective* exemption provision of Section 360k(b) (allowing the FDA to preserve otherwise-preempted state requirements), not the intricate backward-looking procedure plaintiffs suggest.

Third, plaintiffs assert that their claims are not preempted because Medtronic could cease marketing the Model 4011, thereby avoiding imposition of different or additional state requirements. Resp. Br. 36. In *Cipollone*, *Easterwood*, and numerous other preemption cases, the defendant also could have avoided imposition of inconsistent state and federal requirements by discontinuing activity that the federal law allows, yet the Court nonetheless affirmed preemption. Furthermore, the resolution that plaintiffs suggest is particularly untenable under the FDCA preemption provision, because its entire purpose is to

prevent state law from driving valuable devices such as the Model 4011 off the market or discouraging their innovation. It is ridiculous to suggest that a provision enacted for this purpose would deny preemption by inducing manufacturers to stop marketing potentially life-saving devices.[8]

IV. PREEMPTION IS CONSISTENT WITH THE STATUTORY SCHEME

Plaintiffs' view of the statute presents a fundamental contradiction. On the one hand, plaintiffs identify a single purpose for the MDA—protection of consumers in light of public health tragedies associated with the Dalkon Shield "IUD." Cross-Pet. Br. 3. On the other hand, they argue that the 510(k) process (which applies to 98 percent of the new devices entering the market each year, see Cross-Pet. Br. 44) does not regulate safety and effectiveness at all and leaves the public completely at risk. Plaintiffs' view of the MDA renders the statutory scheme irrational, because it mandated that the majority of new devices (i.e., those in Class I and II) *must* enter the market through the 510(k) process. Plaintiffs also cannot explain why, if the statute is focused exclusively on enhancing safety and effectiveness, the preemption provision's text prohibits state requirements that "relate[] to * * * safety or effectiveness" (21 U.S.C. 360k(a)) even if they are "more stringent than a requirement under [the FDCA]" (*id.* § 360k(b)). Indeed, under plaintiffs' reading of the statute, the preemption provision has no ascertainable purpose at all.

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[8] The Court also should reject plaintiffs' suggestion that manufacturers might simply endure tort judgments *without* taking a device off the market, because "it is often beneficial to society as a whole both to keep the product on the market *and* to compensate injured parties through the tort system." Resp. Br. 13. In the real world, tort suits have created a powerful incentive to discontinue marketing of valuable medical devices, as the amicus brief of the Health Industry Manufacturers Association explains. HIMA Br. 25-28. Moreover, the decision to continue marketing a device found to be defective might subject a manufacturer to crippling punitive damages awards.

Plaintiffs' construction also deems the FDA's administration of the statute irrational, because the Agency has chosen to regulate some Class III devices, such as pacemaker leads, through the 510(k) process for the time being rather than requiring PMAs. Moreover, given their characterization of the 510(k) process, plaintiffs can offer no rational explanation why the FDA, following the Dalkon Shield tragedy, continued to regulate IUDs through the 510(k) process for a decade after Congress enacted the MDA, although the Agency could have required PMAs years earlier. See 21 C.F.R. 884.5360(d) (imposing PMA requirements for IUDs on August 4, 1986).

In fact, the statute establishes a very rational plan, and the preemption provision has an overwhelmingly important purpose. The statute promotes the health of the society as a *whole* by substituting a protective federal scheme (which promotes device innovation and availability) for the right of *individuals*—such as Mrs. Lohr—to seek relief under state law for injuries from medical devices. Congress understood that excessive state regulation (whether through common law claims or positive law) would threaten the greater good by inhibiting new technological advances and driving existing beneficial technologies off the market. Under the statute, the interests of the *few* in obtaining tort compensation give way to the interests of the *many* who benefit from life-enhancing technologies made more available by a broad "prohibition on non-Federal regulation." H.R. Rep. No. 853, at 45. The preemption of common law claims therefore is not an inadvertent by-product of the statute, but instead the result of a well-reasoned structure that fosters providing the society at large with the most advanced technology to enhance public health.[9]

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[9] The present case is easily distinguishable from *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), in which the Court construed a statute that strikes a different balance between state and federal law than does the FDCA. Although acknowledging a "tension" between state damages actions and exclusive federal regulatory authority (464 U.S. at 256), the Court in *Silkwood*

(Footnote cont'd on next page)

In reaching this decision, Congress tailored the preemption provision to the particular characteristics of the relatively young medical device industry, which was then, as it is now, comprised largely of small, innovative companies. See, e.g., MDMA Brief 6. These small companies, most burdened by excessive regulation, historically have been the major source of innovation in the industry. See H.R. Rep. No. 853, at 12, 33 (recognizing contribution of small manufacturers to important innovations). Although plaintiffs may speculate about why Congress did not also enact an express preemption provision applicable to the products of other FDA-regulated industries, see Resp. Br. 2-3, it is clear that the device industry's vulnerability to over-regulation (and the resulting adverse consequences for public health) motivated the enactment of Section 360k.[10] In any event, it is clear that Congress *did* enact a preemption provision for medical devices, but not for various other FDA-regulated products, and this is not the proper forum to debate Congress's wisdom in making these legislative choices.

(Footnote cont'd from previous page.)

held that there was no preemption because it found that "Congress intended * * * to tolerate [such] tension" (*ibid.*) under the Atomic Energy Act of 1954. In particular, the Court read the Price-Anderson Act—which establishes an indemnification scheme for nuclear operators held liable under state tort law—to constitute affirmative evidence of Congress's acceptance of state tort actions (*id.* at 251-256). Furthermore, the Atomic Energy Act contains no preemption provision and in fact explicitly preserves significant authority for the states (e.g., 42 U.S.C. 2018, 2021(b), 2021(k)).

In addition, the sole question in *Silkwood* was whether federal law preempted state *punitive* damages awards. It was common ground among the Justices that Congress intended to permit state tort claims for *compensatory* damages. Thus, *Silkwood* involved the availability of a particular remedy, not the question whether a state tort action was foreclosed by federal law.

[10] The same concern led Congress to include a provision in the MDA establishing a specific FDA office to assist small manufacturers. See Pub. L. No. 94-295, sec. 10, 90 Stat. 539, 583 (1976).

Furthermore, to ensure prompt protection from over-regulation, Congress made the preemption clause effective immediately upon enactment of the MDA, without waiting for the FDA to promulgate regulations. See, e.g., H.R. Rep. No. 853, at 45-46 (California PMA statute preempted). But see Resp. Br. 27-28 (asserting that, until federal PMAs are in place, states may require PMAs for some devices). To be sure, Medtronic agrees with plaintiffs that a federal requirement must exist for the preemption clause to apply. But the statute itself imposed numerous requirements at the time of enactment, and the number of requirements has grown subsequently as the Agency has promulgated new regulations. In any event, extensive federal requirements certainly were in place regulating the design of the Model 4011 by the time the FDA authorized its marketing.

Finally, just as it prohibited *state* requirements through the preemption provision, Congress substantially augmented the *federal* regulatory structure to meet its goal of protecting the public from unsafe and ineffective devices. Substantive requirements such as the GMP and labeling regulations are integral to Congress's plan. The 510(k) process also is fundamental to this structure. For devices such as the Model 4011, the 510(k) process assures that safety and effectiveness is comparable to that of a preamendment device. Pet. Br. 23-27.

In order to make certain that this comparative level of safety and effectiveness is meaningful, Congress and the FDA have established a panoply of federal requirements governing the safety and effectiveness of preamendment devices. Through these requirements, some of which are described in Medtronic's opening brief and the attached appendix, the FDA has broad authority to take unsafe and ineffective preamendment devices off the market. Pet. Br. 5-10; App. 1a. By assuring safety and effectiveness comparable to a preamendment device, the 510(k) process bars marketing of devices less safe or effective than those that have stood the test of time in a heavily regulated marketplace. Plaintiffs' pretense that these substantial requirements governing preamendment devices do not exist (see

Resp. Br. 24, 37 n.11) and disingenuous suggestion that premarket clearance provisions are the *only* means of protecting the public from risky devices, simply ignore significant requirements that (in conjunction with the 510(k) process) are designed to promote the safety and effectiveness of 510(k) devices.[11]

The statute's language, structure and legislative history demonstrate that Congress struck a delicate balance between the need for enhanced federal requirements and the need to prohibit state requirements. Although reasonable people may disagree whether the 510(k) process and the allied protective requirements are the ideal system for regulating device safety and effectiveness, that issue is not before the Court. As long as those requirements are applicable to the Model 4011, they are preemptive. This Court should follow the mandate of the statutory language and conclude that plaintiffs' design claims are preempted, because they would impose state requirements relating to device design that are different from, or in addition to, those federal requirements.

CONCLUSION

The Court should reverse in part the judgment of the Eleventh Circuit and hold that the FDCA preempts plaintiffs' design defect claims.

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[11] Indeed, plaintiffs' selective presentation of the federal requirements leads to the absurd conclusion that the FDA would be powerless to prevent the marketing of a 510(k) device if it is substantially equivalent to an *unsafe* preamendment device. Resp. Br. 34-35. Under these circumstances, the FDA merely would inform the applicant that, although the device under review is substantially equivalent, it would violate other FDCA provisions to market the device. See, e.g., HIMA Br. App. B; cf. 21 U.S.C. 360c(i)(2) ("A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.").

Respectfully submitted,

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APPENDIX

APPENDIX: SELECTED DEVICE REQUIREMENTS

REQUIREMENT	PRE[a]	510(k)	PMA
Adulteration[1]	X	X	X
Misbranding[2]	X	X	X
Labeling (general)[3]	X	X	X
Labeling (prescription)[4]	X	X	X
Good Manufacturing Pract.[5]	X[b]	X[b]	X
Notification of Hazard[6]	X	X	X
Repair, Replace, Refund[7]	X	X	X
510(k) Clearance[8]		X	
Medical Device Reporting[9]	X[c]	X[c]	X
Device Listing[10]	X[c]	X[c]	X
Seizure, Injunction[11]	X	X	X
Factory Inspection[12]	X	X	X

Note: X denotes that requirement applies to device type.

[a] Preamendment device.

[b] FDA has statutory authority to exempt Class I devices from this requirement and has exercised that authority by regulation for numerous device types.

[c] FDA has statutory authority to exempt Class I devices from this requirement but has not yet granted any exemptions by device type.

[1] 21 U.S.C. 351 (7 separate requirements).

[2] 21 U.S.C. 352 (10 separate requirements).

[3] 21 U.S.C. 321(n), 352, 360f(a)(2); 21 C.F.R. Pts. 1, 801.

[4] 21 U.S.C. 321(n), 352, 360f(a)(2); 21 C.F.R. Pts. 1, 801.

[5] 21 U.S.C. 351(h), 360j(f); 21 C.F.R. Pt. 820.

[6] 21 U.S.C. 352(t), 360h(a).

[7] 21 U.S.C. 352(t), 360h(b).

[8] 21 U.S.C. 352(o), 360(k), 360c(f)(1), 360c(i); 21 C.F.R. Pt. 807.

[9] 21 U.S.C. 352(t), 360i; 21 C.F.R. Pt. 803.

[10] 21 U.S.C. 352(o), 360(j); 21 C.F.R. Pt. 807.

[11] 21 U.S.C. 331, 332, 334.

[12] 21 U.S.C. 374.

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Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.
Petitioner/Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writ of Certiorari to the
United States Court of Appeals for the Eleventh Circuit

REPLY BRIEF FOR CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

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April 16, 1996

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

REPLY BRIEF FOR CROSS-PETITIONERS 1

ARGUMENT 4

I. 21 U.S.C. 360k(a) DOES NOT PREEMPT DAMAGES CLAIMS. 4

A. Damages Claims Do Not Impose Requirements "With Respect To A Device." 5

B. The Multiple Uses Of "Requirement" In Section 360k Further Bolster The Lohrs' Position. 8

C. Section 360h(d) Further Demonstrates That Damages Claims Are Not Preempted. 10

II. EVEN IF SECTION 360k(a) PREEMPTED SOME DAMAGES CLAIMS, IT WOULD NOT PREEMPT THE LOHRS' FAILURE-TO-WARN AND MANUFACTURING-DEFECT CLAIMS. 11

A. The Lohrs' Claims Are Not Preempted Because The Applicable Federal Requirements Are Neither Device-Specific Nor Subject-Specific 11

B. None Of The Provisions Of Federal Law Relied On By Medtronic Preempts The Lohrs' Claims. 12

1. The Failure-To-Warn Claim 12

2. The Manufacturing-Defect Claim 15

III. THE LOHRS' CLAIMS ARE NOT PREEMPTED INSOFAR AS THEY RELY ON FEDERAL STANDARDS. 17

CONCLUSION 20

TABLE OF AUTHORITIES

CASES

Pages

Atlantic Coast Line R.R. v. Brotherhood of Locomotive Engineers, 398 U.S. 281 (1970) 18

California v. Zook, 336 U.S. 725 (1948) 18

Chevron U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984) 19, 20

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 2, 4, 10, 14

Corn Products Refining Co. v. Eddy, 249 U.S. 427 (1919) 19

English v. General Electric Co., 496 U.S. 72 (1990) 4

Freightliner Corp. v. Myrick, 115 S. Ct. 1483 (1995) 15

Gulf Offshore Co. v. Mobil Oil Corp., 453 U.S. 473 (1981) 18

Hillsborough County v. Automated Medical Labs., Inc., 471 U.S. 707 (1985) 3

Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) 19

Loughan v. Firestone Tire & Rubber Co., 749 F.2d 1519 (11th Cir. 1985) 13

Morse v. Republican Party of Virginia,
__ U.S. __ (1996) 7

Perez v. National Presto Indus., Inc.,
431 So. 2d 667 (Fla. App. 1983) 13

Rice v. Norman Williams Co.,
458 U.S. 654 (1982) 13

Silkwood v. Kerr-McGee Corp.,
464 U.S. 238 (1984) 9

Sullivan v. Stroop,
496 U.S. 478 (1990) 8

STATUTES AND BILLS

15 U.S.C. 4406 10

21 U.S.C. 360h(a) 14

21 U.S.C. 360h(a)(2) 10

21 U.S.C. 360h(b) 3, 10

21 U.S.C. 360h(b)(2)(C) 3, 10

21 U.S.C. 360h(b)(3) 3

21 U.S.C. 360h(d) 1, 2, 3, 10

21 U.S.C. 360k 1

21 U.S.C. 360k(a) 1, 2, 4, 11, 20

21 U.S.C. 360k(a)(2) 6

21 U.S.C. 360k(b) 2

S. 510, 94th Cong., 1st Sess. (1975) 18

Cal. Health & Safety Code 110105 19

Cal. Health & Safety Code 110175 15

Cal. Health & Safety Code 111245 19

Cal. Health & Safety Code 111325 19

Cal. Health & Safety Code 111550(a) 19

Fla. Stat. Ann. 499.002(2) 19

Fla. Stat. Ann. 499.002(3) 19

Fla. Stat. Ann. 499.013(2)(d)1 19

Fla. Stat. Ann. 499.055(2) 15

N.Y. Educ. Law 6802(13) 19

N.Y. Gen. Bus. Law 640(1)(d) 19

REGULATIONS

21 C.F.R. 801.109(c) 12

21 C.F.R. 801.430 17

21 C.F.R. Part 807 14

21 C.F.R. 807.87(e) 15

21 C.F.R. 807.87(k) 15

21 C.F.R. 808.1(d) 11, 12, 16

21 C.F.R. 808.1(d)(2) 18, 19, 20

21 C.F.R. 808.1(d)(6)(ii) 9

21 C.F.R. 808.1(f) 6

21 C.F.R. 808.5(b)(2) 9

21 C.F.R. 808.20(a) 9

21 C.F.R. 808.20(c)(1) 9

21 C.F.R. 814.39(d)(2)(i)-(iv) 14

21 C.F.R. 820.160 16

21 C.F.R. 820.162 16

43 Fed. Reg. 18661 (May 2, 1978) 2, 5, 6, 19, 20

44 Fed. Reg. 19438 (Apr. 3, 1979) 6

45 Fed. Reg. 67321 (Oct. 10, 1980) 15, 20

53 Fed. Reg. 52789 (Dec. 29, 1988) 6

Fla. Admin. Code Ann. 10D-45.043(5) 13

LEGISLATIVE HISTORY

H.R. Rep. 853, 94th Cong., 2d Sess. 2, 6, 8, 10

MISCELLANEOUS

Kahan,
Premarket Approval Versus Premarket Notification: Different Routes to the Same Market,
39 Food Drug Cosm. L.J. 510 (1984) 15

Wright,
Federal Courts (4th ed. 1983) 18

REPLY BRIEF FOR CROSS-PETITIONERS

Cross-respondent Medtronic, Inc., begins its brief in No. 95-886 claiming that the Lohrs have ignored the text of the Medical Device Amendments ("MDA") and have improperly focused their arguments on the MDA's purposes. That accusation is inaccurate. In meticulous detail, the Lohrs have analyzed the entire MDA (Lohr Open. Br. 2-7), including its preemption language, 21 U.S.C. 360k (*id.* at 16-27), its "savings" provision, 21 U.S.C. 360h(d) (*id.* at 27-28), the 510k "substantial equivalence" process (*id.* at 34-38), and the body of regulations and rulings issued by the Food and Drug Administration ("FDA") concerning the MDA's preemptive reach. *Id.* at 39-41; *see also* Brief of Respondents in No. 95-754 ("Lohr Resp. Br.") at 6-12, 15-37.

Medtronic is correct, however, that the parties "have taken two markedly different approaches" to this case. Med. Resp. Br. 1. Medtronic claims that the MDA preempts all state medical device law—*even state law based on the same substantive standards as federal law.* *Id.* at 38-49. In contrast, the Lohrs, joined by the Solicitor General, maintain that had Congress wanted to eliminate state law entirely it would have said just that, rather than what it did say: that state law is preempted only where it is "different from, or in addition to" federal law. 21 U.S.C. 360k(a). Similarly, Medtronic bases its preemption claim on general federal regulations that are entirely consistent with the Lohrs' state-law claims and on a grab-bag of *potential* MDA enforcement mechanisms, some of which have no relationship to the subject-matter of the Lohrs' claims and none of which has ever been invoked with respect to Medtronic's Model 4011 pacemaker lead. The Lohrs, however, look to the text of section 360k(a), under which preemption occurs only when a state medical device requirement *is* different from, or in addition to, a federal device requirement, and then only where the federal requirement is applicable, not *potentially* applicable, to the device in question.

See U.S. Br. 23; *see also* 43 Fed. Reg. 18661, 18662 (May 2, 1978)("[t]he phrase 'or in addition to, any requirement applicable under this Act to the device' means that an FDA requirement must exist before preemption can occur").

Further, Medtronic fixates on one word—"requirement"—in 21 U.S.C. 360k(a). The Lohrs, however, read that word as part of the sentence in which Congress placed it, in conjunction with its companion provision, 21 U.S.C. 360k(b), and as part of the entire statute, including 21 U.S.C. 360h(d), which preserves state-law damages liability and which is meaningless if section 360k(a) preempts all state tort law in medical device cases.

To be sure, the Lohrs do not ignore the history and purpose of the MDA because "[t]he ultimate question in each [preemption] case is one of Congress's intent, as revealed by the text, structure, purposes, and subject matter of the statute involved." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545 (1992)(Scalia, J., concurring in the judgment in part and dissenting in part)(citations omitted). The MDA was enacted against a backdrop of serious device failures in which tort litigation played an important role expressly acknowledged by Congress, *see, e.g.*, H.R. Rep. 853, 94th Cong., 2d Sess. 8 (1976)("*House Report*"); neither the text of the MDA nor the debate leading to its passage even hints that Congress was providing device manufacturers with tort immunity; and the legislative history of the MDA refers *solely* to the preemption of positive state law, not tort law. *See id.* at 45-46.

Medtronic's only response is that Congress *might* have eliminated state tort law if it had given that topic any thought. "Members of Congress thinking rationally," Medtronic contends, "could easily conclude" that, in the interest of uniformity, it would be best to eliminate all compensation for harms caused by faulty medical devices. Med. Resp. Br. 3-4. Whether a rational

Congress "could" come to such a conclusion is doubtful; that the 94th Congress did *not* come to such a conclusion is beyond debate. There is *no* evidence, let alone the crystal clear textual evidence that this Court's precedents require, *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 715 (1985), for the wholesale preemption of state tort law that Medtronic seeks here.

Medtronic asserts that this Court has frequently countenanced preemption of state tort law by federal legislation that does not provide a damages remedy; in fact, *no* decisions of this Court stand for that proposition. The precedents cited by Medtronic, *see* Med. Resp. Br. 5, concern preemption of state law where a federal statute—like the Jones Act or ERISA—*does* provide a private right of action for damages, although not always precisely the same relief otherwise available under state law. There should be no mistake about the unprecedented result sought by Medtronic: elimination of *all* damages remedies for consumers injured by medical devices, a result at odds with the text, structure, history, and purpose of the MDA.[1]

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[1] Medtronic asserts that 21 U.S.C. 360h(b)—which, the FDA informs us, has *never* been invoked in the 20-year history of the MDA—provides a federal damages remedy that would enable Lora Lohr to recover for her injuries. Med. Resp. Br. 5 n.5. Contrary to Medtronic's claim, remedies under section 360h are wholly within the FDA's discretion and *cannot* be invoked by consumers. Moreover, for persons already injured by medical devices (*i.e.*, tort plaintiffs), section 360h(b) could only provide a refund of the device's purchase price. *See* 21 U.S.C. 360h(b)(2)(C). Thus, despite Medtronic's assertion to the contrary, the "reasonable and foreseeable expenses ... incurred in availing [her]self of that remedy," *id.* 360h(b)(3), would not include Ms. Lohr's medical expenses, let alone her lost wages, future medical care, physical pain and scarring, Mr. Lohr's loss of consortium, and other actual damages. *See* Complaint, ¶¶ 2, 15-16, RE 2, 4. Medtronic's claim that section 360h(b) provides a rationale for the elimination of state tort law is all the more absurd in light of 21 U.S.C. 360h(d)(discussed *infra* at 10), which *preserves* state-law damages liability even

(continued...)

In its brief as cross-respondent, Medtronic argues that (1) section 360k(a) preempts damages actions; (2) the MDA contains "requirements" that preempt the Lohrs' failure-to-warn and manufacturing-defect claims; and (3) the Lohrs' damages claims are preempted under section 360k(a) even if they are based on the very federal standards that Medtronic claims have preemptive effect. None of Medtronic's contentions is correct.

ARGUMENT

I. 21 U.S.C. 360k(a) DOES NOT PREEMPT DAMAGES CLAIMS.

In maintaining that damages actions are within the reach of 21 U.S.C. 360k(a), Medtronic wrongly accuses the Lohrs of rearguing issues resolved by the Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). Although the word "requirement" appears in one of the statutes at issue in *Cipollone* and in section 360k(a), nothing else about the text, structure, or history of the two provisions is alike, and all indications are that damages actions are not preempted by section 360k(a). *See* Lohr Open. Br. 16-34; Lohr Resp. Br. 8-15. We reply here only to the new arguments made by Medtronic and by the Solicitor General.

---

[1](...continued)
after a manufacturer has complied with a refund or repair order. *See also English v. General Electric Co.*, 496 U.S. 72, 75-76 & n.2, 87-90 (1990)(federal administrative remedy for "whistle-blowers" providing back pay, compensatory damages, attorney's fees and costs, and judicial review in federal court, did not preempt state-law tort claim for wrongful discharge because "[o]rdinarily, the mere existence of a federal regulatory or enforcement scheme, even one as detailed as [this one], does not by itself imply pre-emption of state remedies").

A. *Damages Claims Do Not Impose Requirements "With Respect To A Device."*

Section 360k(a) preempts only state-law requirements "with respect to a device." While device requirements contained in state statutes, regulations, and ordinances ordinarily *require* a manufacturer to take some action "with respect to a device," such as removing it from the market, a damages action, if successful, only *requires* the manufacturer to compensate the plaintiff. *See* Lohr Open. Br. 19-21. Damages actions thus "are not requirements 'with respect to a device' within the meaning of section [360k(a)] because they generally pertain ... to persons who manufacture devices or distribute devices..., and not directly to devices. In order for a State provision to be a requirement with respect to a device within the meaning of section [360k(a)]—and thereby a candidate for preemption—it must relate to the device itself." 43 Fed. Reg. at 18663.

Medtronic and the United States do not dispute that, if the phrase "with respect to a device" modifies "requirement," common-law damages actions would not be preempted under section 360k(a). They argue *only* that "the 'with respect to' phrase cannot modify the word 'requirement' because 'requirement' comes *after* that phrase. Rather, the phrase modifies the words ('establish or continue in effect') that come immediately before it." U.S. Br. 17-18; *see* Med. Resp. Br. 14. This interpretation of section 360k(a)'s text is incorrect for several reasons.

First, as a matter of grammar, Medtronic is simply wrong. "With respect to" modifies "requirement" because "with respect to" is an adjectival phrase describing a trait of the noun "requirement." "With respect to" is not an adverbial phrase because it does not describe how a verb is performed. Therefore, it does not modify the verbs "establish" or "continue."

Second, authoritative interpretations of section 360k(a), including the contemporaneous explanation of the House Committee from which section 360k(a) emerged, make clear that "with respect to" modifies "requirement." *See House Report*, at 45. The FDA's regulations and preemption rulings have understood section 360k(a) in this same manner.[2]

Third, contrary to Medtronic's claim, no grammatical rule requires a modifier to come after the word it is modifying, rather than before it. It is not unusual for a modifier to come before the word being modified, as in a portion of the Eleventh Circuit's opinion quoted by the Solicitor General which refers to "preemption-triggering requirements." U.S. Br. 9.

Finally, Medtronic's locution makes no sense. The company claims that Congress needed to modify "establish or continue in effect" with "with respect to a device" to protect a state's ability to enact and enforce laws that address other products in addition to medical devices. But 21 U.S.C. 360k(a)(2) *already* makes clear that the state requirement must "relate" to devices. Moreover, the notion that Congress needed to re-emphasize that the MDA does not preempt laws when they do not regulate medical devices is ludicrous; obviously, the MDA cannot preempt state regulation of, say, lawnmowers or boats.

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[2] *See, e.g.*, 21 C.F.R. 808.1(f); 53 Fed. Reg. 52789, 52790 (Dec. 29, 1988)(Missouri statute prohibiting sale of hearing aids by mail not preempted by federal law because "it is not a requirement with respect to a device" under section 360k(a)); 44 Fed. Reg. 19438, 19439-19440 (Apr. 3, 1979); 43 Fed. Reg. at 18663 ("State laws relating to inspection, registration, and licensing usually are not requirements 'with respect to a device' within the meaning of section [360k] of the act because they generally pertain either to persons who manufacture or distribute devices or to places where devices are manufactured, and not directly to devices").

Compounding its erroneous parsing of the statute, Medtronic—but not the United States—claims that if "with respect to a device" modified "requirement," section 360k(a) could preempt state statutes only if they apply *solely* to medical devices, but not if they regulate more than one type of product, for instance drugs and devices. Med. Resp. Br. 15. Nothing of the sort follows. To use the company's example, state device regulation under a statute that governs both devices and drugs can still be preempted, if the specific regulation at issue *requires* the manufacturer to take action *with respect to a device*. Section 360k(a) does not preempt the Lohrs' damages claims, however, because a favorable judgment will *not*, under any circumstances, require Medtronic to take any action with respect to its Model 4011 pacemaker lead.[3]

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[3] This Court's recent decision in *Morse v. Republican Party of Virginia*, __ U.S. __ (1996), provides further support for the Lohrs' position that damages claims are not preempted because they are not issued by a "State or political subdivision of a State" within the meaning of section 360k(a). *See* Lohr Resp. Br. 10-12. In *Morse*, five members of this Court focused on the purpose and history of the Voting Rights Act to conclude that the phrase "State or political subdivision" brought some activities of political parties within the reach of section 5 of the Act. Opinion of Stevens, J., slip op. at 32; Opinion of Breyer, J., slip op. at 3. Likewise, in this case, the purpose and history of the MDA compel the conclusion that "State or political subdivision of a State" does not include damages verdicts rendered by state and federal juries and judges. *See* Lohr Open. Br. 28-33.

Four members of the Court in *Morse* focused on "the plain meaning" of section 5, as confirmed by other provisions of the Voting Rights Act, to find that "State or political subdivision" applies only to geographical units of state governments, not political parties. Opinion of Thomas, J., slip op. at 1-4; Opinion of Kennedy, J., slip op. at 2, 6. This reading also supports the Lohrs' position in this case, since judges and juries are not units of the state, let alone geographical units. *See* Lohr Resp. Br. 10-12; *see also* Lohr Open. Br. 16-28.

B. The Multiple Uses Of "Requirement" In Section 360k Further Bolster The Lohrs' Position.

1. The parties agree that sections 360k(a)(1) and 360k(a)(2) each use the word "requirement" to describe the kind of positive federal laws that can have preemptive effect—the MDA and regulations thereunder. Those uses of "requirement" plainly exclude damages claims. Section 360k(a) also uses "requirement" a third time to describe actions taken by states concerning medical devices. Because multiple uses of the same word in the same Act—*here, the same sentence*—are ordinarily accorded the same meaning, *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990), state-law "requirements" under section 360k(a) do not go beyond positive law to include damages actions.

Medtronic argues, however, that the statute's federal "requirements" are accompanied by a modifier ("applicable under [the FDCA] to the device"), while the state "requirements" are not. But it is much more logical for Congress to have omitted the modifiers for state requirements as unnecessary because of the rule of construction on which the Lohrs rely, namely, that unless Congress provides to the contrary, the same word means the same thing throughout an Act. Thus, there is no reason to believe that the range of state law subject to preemption is any different from the range of federal law given preemptive effect.[4]

2. Medtronic's interpretation of section 360k(b) is similarly flawed. The company concedes that the texts of sections 360k(a) and 360k(b) are coextensive—that is, that anything preempted

[4] This conclusion is buttressed by the legislative history, which refers *only* to state statutes and regulations as candidates for preemption, *House Report*, at 45-46, and the FDA's regulations and regulatory commentary, which make repeated references to the preemption of state positive law, but do not mention preemption of state tort law. *See* Lohr Open. Br. at 25-27.

under 360k(a) can be exempted from preemption under 360k(b)—and that it would be "very difficult" to obtain an exemption for damages actions under section 360k(b). Med. Resp. Br. 16. It then argues, however, in contradiction to its concessions, that perhaps Congress (without saying so) did not actually intend to permit exemptions for damages claims. *Id.* Thus, in Medtronic's view, preemption of damages claims is a one-way street: all claims would be preempted, but none could be exempted. However, according *less* protection from the incursions of federal law to damages claims than to positive law stands this Court's jurisprudence on its head. The Court has consistently held, in light of the fundamental differences between direct state regulation and tort compensation, that preemption of tort remedies occurs only where the text or structure of the Act unmistakably demands that result. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Moreover, Medtronic provides no rational basis for Congress to have used the same "requirements" language in sections 360k(a) and 360k(b) if it intended the scope of the two sections to be dramatically different. Nor does the company explain how such a scheme can be squared with the FDA's regulations, 21 C.F.R. 808.1(d)(6)(ii), 808.5(b)(2), 808.20(a), 808.20(c)(1), which indicate that sections 360k(a) and 360k(b) are co-extensive and refer only to statutes, regulations, and ordinances as candidates for preemption and exemption from preemption. *See* Lohr Open. Br. 25-27. The only reasonable explanation of the whole provision is the one demanded by its text, structure, and purpose: Sections 360k(a) and 360k(b) encompass the same "requirements," and neither includes state-law damages actions.

C. Section 360h(d) Further Demonstrates That Damages Claims Are Not Preempted.

Under 21 U.S.C. 360h(d), "compliance with an [FDA] order" under section 360h directing a manufacturer to issue a notification, or to repair, replace, or reimburse the purchase price of a device, "shall not relieve any person from liability under ... State law." Medtronic argues that this provision has "nothing to do with tort liability" and applies only to contract actions among manufacturers and their distributors and suppliers. Med. Resp. Br. 18 & n.18. But section 360h plainly applies to device users, *i.e.*, potential tort plaintiffs. For example, 21 U.S.C. 360h(b)—which authorizes the FDA to order device repair and replacement—concerns costs incurred by patients. *E.g.*, *id.* 360h(b)(2)(C); *see House Report*, at 23. And 21 U.S.C. 360h(a)(2) authorizes notification of device risks to "individuals subject to the risk"—device consumers. Thus, Medtronic offers no explanation of how elimination of all tort liability can be squared with the text of section 360h(d)—which preserves state-law claims for damages, even *after* the FDA has ordered a manufacturer to provide a notification, repair, or refund.[5]

[5] The presence of 21 U.S.C. 360h(d) further distinguishes this case from *Cipollone*, where the plurality relied on the *absence* of a savings provision as evidence that the statute at issue there preempts *some* damages actions. *Cipollone*, 505 U.S. at 523 n.22. *Cipollone* also noted that the savings provision of the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. 4406—whose wording is similar to section 360h(d)—broadly preserves damages actions. *Cipollone*, 505 U.S. at 518; *see also id.* at 537 n.2 (separate opinion).

II. EVEN IF SECTION 360k(a) PREEMPTED SOME DAMAGES CLAIMS, IT WOULD NOT PREEMPT THE LOHRS' FAILURE-TO-WARN AND MANUFACTURING-DEFECT CLAIMS.

A. The Lohrs' Claims Are Not Preempted Because The Applicable Federal Requirements Are Neither Device-Specific Nor Subject-Specific.

Under 21 U.S.C. 360k(a), and its implementing regulation, 21 C.F.R. 808.1(d), for preemption to occur, a federal requirement must address the same subject matter and the same type of device as the relevant state-law requirement. *See* Lohr Open. Br. 39-44. Medtronic does not dispute that the Lohrs' claims are not preempted under section 808.1(d), but asserts that the regulation is not a valid interpretation of section 360k(a). We have previously shown that the FDA regulation is a reasonable interpretation of section 360k(a) that is entitled to deference. *See id.* 40-42; Lohr Resp. Br. 20-22. One point bears emphasis here because it demonstrates the fallacy of Medtronic's position.

Other than an isolated claim that *any* federal requirement preempts *all* state requirements (Med. Resp. Br. 19), the thrust of Medtronic's position is that state law pertaining to particular subject matters is preempted because the FDA regulates, or at least has the power to regulate, those same subject matters. (For instance, the company argues that the good manufacturing practice guidelines preempt all state law concerning device manufacture.) Although, as shown below, Medtronic's approach sweeps far too broadly, the critical point here is that Medtronic itself recognizes that section 360k(a) calls for a subject-matter linkage between the preempting federal requirements and the preempted state requirements, *precisely as 21 C.F.R. 808.1(d) demands.*

Once Medtronic makes that concession, it cannot plausibly contest the validity of 21 C.F.R. 808.1(d) or ignore its implications for the proper construction of the MDA. Section 808.1(d) defines the fit between the state and federal regulations that the text of section 360k(a) demands and insures that the federal requirement concerns the same feature of the medical device (subject-matter specificity) at the same level of generality (device-specificity) as the state requirement. Because no federal requirements demand specific warnings or manufacturing processes for pacemaker leads, the Lohrs' claims are not preempted.

B. None Of The Provisions Of Federal Law Relied On By Medtronic Preempts The Lohrs' Claims.

As shown above, under 21 C.F.R. 808.1(d), the Lohrs' claims are not preempted. Nevertheless, Medtronic argues that the general federal rules regarding device labeling and manufacturing preempt the Lohrs' claims. Even if section 808.1(d) is not dispositive, none of the company's contentions is correct.

1. The Failure-To-Warn Claim.

In urging preemption of the Lohrs' failure-to-warn claim, Medtronic relies chiefly on the FDA's labeling rules for prescription devices. Those rules do not preempt the Lohrs' claim for several reasons.

First, the regulation on which Medtronic relies is not "different from, or in addition to" the Lohr's claim. Under 21 C.F.R. 801.109(c), prescription device labels must contain "any relevant hazards, contraindications, side effects, and precautions." Medtronic attempts to contrast this policy with the Florida common-law duty to provide "fair and adequate warnings" of a product's dangers (Med. Resp. Br. 29), but that duty is obviously not at odds with the federal standard. The company complains that Florida law "could" require warnings that the federal requirement

does not because federal labels need not contain warnings of which doctors are "commonly aware." *Id.* But that general standard is identical to the Florida common-law standard, under which "[a] manufacturer is not compelled to warn knowledgeable [users] of the dangers of which the [user] either knows or should be aware." *Loughan v. Firestone Tire & Rubber Co.*, 749 F.2d 1519, 1525 (11th Cir. 1985)(*quoting Perez v. National Presto Indus., Inc.*, 431 So.2d 667, 669 (Fla. App. 1983)); *cf.* Fla. Admin. Code Ann. 10D-45.043(5)(labels need not provide directions "with respect to common uses, adequate directions for which are known by the ordinary individual").

In any event, "the mere possibility" of conflict with a federal requirement—the basis on which Medtronic urges preemption here—is not enough: Section 360k(a) preempts only where state law "'*is* different from or in addition to' federal requirement." U.S. Br. 23; *see Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)("The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute"). Indeed, the facts of this case demonstrate the wisdom of the Court's rule that preemption must be based on reality, not conjecture: Doctors could not possibly be "commonly aware" of the details of Medtronic's pacemaker lead failures unless they were warned of them, and thus such warnings would have been completely consistent with federal law.

Second, the labeling regulations do not preempt the Lohrs' claim because, under those rules, manufacturers are permitted to augment their labels to enhance safety or to warn of prior product failures. Moreover, the section 510(k) notification process did not require approval of the Model 4011 label or require that it contain any particular statements, just as nothing in the regulations bars a manufacturer from changing its label for a 510(k) product. *See*

generally 21 C.F.R. Part 807. Indeed, *even for devices that have received premarket approval*, manufacturers are expressly permitted to make labeling changes that add or strengthen contraindications and warnings or otherwise enhance consumer safety *without* prior FDA approval. 21 C.F.R. 814.39(d)(2)(i)-(iv). Thus, the Lohrs' duty-to-warn claims are not "different from, or in addition to" applicable FDA labeling rules.

Finally, as the United States has shown (U.S. Br. 27)—but Medtronic has ignored—the FDA's labeling rules do not impose any requirements on modes of communication other than labeling. Even in *Cipollone*, where specific congressionally-mandated label warnings were the centerpiece of a federal law that preempted any "requirement or prohibition based on smoking and health ... imposed under State law with respect to the advertising or promotion of [properly labeled cigarette] packages," 505 U.S. at 515, this Court found no preemption of failure-to-warn "claims that rely solely on [the manufacturer's] ... actions unrelated to advertising or promotion." *Id.* at 524-25. Thus, at a minimum, the MDA does not preempt a claim that Ms. Lohr and her physicians should have been warned by means other than the product label.[6]

---

[6] Medtronic makes two other bids for preemption of the failure-to-warn claim. First, the company relies on FDA *authority* to take certain actions, some of which are unrelated to labeling (*e.g.*, authority to seize products), and *none* of which the FDA has taken concerning the Model 4011 lead. Med. Resp. Br. 24. Medtronic claims that the FDA has "exclusive authority" under 21 U.S.C. 360h(a) to notify the public about device hazards (Medtronic Br. 28 n.29), but nothing in the text makes the FDA's role "exclusive." In fact, the FDA ruled in a formal advisory opinion that a suit seeking a worldwide notification to device users under state common law was not preempted. *See* Lohr Open. Br., App. 12a-13a. In addition, the agency has formally advised states that their laws granting "authority to disseminate information for the health and safety of" (continued...)

2. The Manufacturing-Defect Claim.

Although Medtronic concedes that there are no MDA requirements relating specifically to the manufacture of pacemaker leads, it nevertheless argues that the federal good manufacturing practice rules ("GMPs")—applicable to virtually all medical devices—preempt the Lohrs' manufacturing-defect claim. The Lohrs' opening brief (at 43-44) showed that, because the MDA's regulation of device manufacture is drawn in such general terms, "state common-law standards governing defective manufacture ... are [not] different from, or in addition to, the applicable GMPs or any other federal requirements." U.S. Br. 23. We rely on our opening brief and add only three points in reply to Medtronic.

First, Medtronic's principal claim is that the Florida common-law duty to produce a non-defective product is preempted because that duty is satisfied only by proof of a dangerous defect,

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[6](...continued)
medical device users are not preempted. 45 Fed. Reg. 67321, 67322 (Oct. 10, 1980); *see, e.g.*, Cal. Health & Safety Code 110175; Fla. Stat. Ann. 499.055(2). And, in any event, federal authority that has not been invoked cannot preempt state law. *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1486 (1995).

Second, Medtronic confuses the *submission* of proposed labeling in a 510(k) notification with FDA *approval* of labeling, which, as the United States notes, does not occur for devices marketed under section 510(k). *See* U.S. Br. 28. Medtronic's 510(k) notification was supposed to contain labeling "sufficient to describe the device, its intended use, and the directions for its use" because that information helps show "whether or not the device is substantially equivalent to a device in commercial distribution." 21 C.F.R. 807.87(e), (k). Labeling is useful in assessing substantial equivalence because the FDA does *not* require submission of a device specimen or any clinical data about how the device actually performs. *See* Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510, 516 (1984)("a 510(k) applicant conceptually need not even have an actual device in existence")(quoting testimony of FDA Commissioner to that effect). Because the 510(k) process does not impose *any* requirements with respect to the *content* of labeling, it cannot possibly preempt the Lohrs' failure-to-warn claim.

while the GMPs can be violated even in the absence of such a danger. Med. Resp. Br. 36. But the fact that the Florida common-law duty may be narrower than that under the GMPs does not make the Lohrs' claims "different from, or in addition to" the GMPs, and certainly does not pose any threat to federal law, which is the rationale for preemption in the first place.

Second, despite Medtronic's citation to numerous GMP rules (*id.* at 33), the actual content of those rules is conspicuously absent from its brief. The Lohrs' opening brief (at 44-45) discussed some of the GMPs, showing that they are general guidelines concerning the manufacture of any consumer product and thus could not possibly be at odds with the Lohrs' manufacturing-defect claim. *See also* U.S. Br. 24. For example, a claim that the Model 4011 was not manufactured to specifications could hardly be "different from, or in addition to" GMP rules on that topic: that testing of devices "be based on an acceptable statistical rationale," 21 C.F.R. 820.160, and that "any failure" of a device to "meet performance specifications be investigated." *Id.* 820.162. The generality of the GMPs not only demonstrates that the Lohrs' claim is not "different from, or in addition to" the GMPs, but also underscores the practical wisdom of the FDA's insistence in 21 C.F.R. 808.1(d) that federal requirements be specific if they are to have preemptive effect. *See* U.S. Br. 24-25.

Finally, Medtronic makes no attempt to show that the Lohrs' manufacturing-defect claim "*is* different from, or in addition to" any particular GMP or any federal device-manufacturing standard, as section 360k(a) demands. U.S. Br. 23. "[T]he mere possibility that a tort plaintiff's defective-manufacture claim might, if successful, effectively be based on a requirement that a device manufacturer do something 'different from, or in addition to,' something required by the general standards enunciated in the

GMPs" does not warrant preemption. *Id.* Accordingly, the Lohrs' manufacturing-defect claim is not preempted.

III. THE LOHRS' CLAIMS ARE NOT PREEMPTED INSOFAR AS THEY RELY ON FEDERAL STANDARDS.

Medtronic maintains that even if the Lohrs' claims are based on the same substantive standards as those provided by the MDA, their claims are preempted. Whatever its other limits, however, section 360k(a) preempts only state device laws that are "different from, or in addition to" applicable federal requirements. For instance, a state labeling regulation for tampons is *different from* the federally-mandated label, *see* 21 C.F.R. 801.430, if the state regulation requires the manufacturer to alter the label's wording in some substantial manner. Similarly, the state regulation would be *in addition to* the federal label if it required that the label contain new material, not contained in 21 C.F.R. 801.430. Yet under Medtronic's reading of section 360k(a), no state could take enforcement action, even if based solely on a manufacturer's failure to use the mandatory tampon label, and no jury could award damages to an injured plaintiff as a result of that failure. Such a result flies in the face of section 360k(a), which preempts state law that imposes requirements "different from, or in addition to"—not the same as—requirements imposed by the MDA.

Medtronic makes several attempts to avoid the statute's plain meaning. First, the company says that *all* state law is "in addition to" federal law. If the mere *existence* of state device laws were itself "in addition to" federal law, however, section 360k(a) would have been written to say simply that "all State law concerning medical devices is preempted."

Second, Medtronic relies on language from preemption provisions of medical device legislation that did *not* become law,

in particular the Senate version of the MDA which preempted certain state device laws unless their "requirements [were] identical to the Federal requirements." S. 510, 94th Cong., 1st Sess. § 704 (1975). If anything, "identical" is *narrower* than "different from, or in addition to," because it arguably demands that the state law be the same as the federal law in its exact wording, as well as in its application. *Compare* 21 C.F.R. 808.1(d)(2).

Medtronic nonetheless claims that only the language in the Senate bill could have preserved state device requirements that are the same as federal requirements. However, if Medtronic is correct that mere state enforcement of federal standards amounts to imposition of a requirement "in addition to" federal requirements, then such enforcement would also entail imposition of a requirement non-"identical" to federal requirements. In fact, with respect to both the Senate bill and to section 360k(a) as enacted, the text is clear that state law that applies substantive standards fully consistent with federal law is not preempted.

Finally, lacking any anchor in section 360k(a), Medtronic argues that courts—particularly "state judges"—will be unable to apply federal law and will preserve claims that ought to be preempted. Med. Resp. Br. 44. Medtronic's distrust of state judiciaries not only defies the presumption against preemption, but is hostile to federalism itself, a central postulate of which is that state and federal courts have co-equal responsibility for enforcing federal law. *Gulf Offshore Co. v. Mobil Oil*, 453 U.S. 473, 477-78 (1981); *Atlantic Coast Line R.R. v. Brotherhood of Locomotive Eng'rs*, 398 U.S. 281, 295-96 (1970); *see* Wright, *Federal Courts* 268-73 (4th ed. 1983). For these reasons, among others, there is generally no preemption where the "case concerns only the state's mechanisms for enforcing a statute identical with that of the federal government." *California v. Zook*, 336 U.S. 725, 736 (1948).

Moreover, Medtronic points to no problems in states where local authorities enforce federal medical device standards. *See, e.g.*, Cal. Health & Safety Code 110105, 111245, 111325, 111550(a); Fla. Stat. Ann. 499.002(2),(3), 499.013(2)(d)1; N.Y. Educ. Law 6802(13); N.Y. Gen. Bus. Law 640(1)(d). Nor is it the case that the regulation of foods, drugs, and cosmetics is in chaos, even though it has long been held that state misbranding and similar laws are not preempted if they are consistent with federal standards. *See, e.g., Corn Products Refining Co. v. Eddy*, 249 U.S. 427 (1919).

This result is also compelled by the FDA's regulations and other authoritative statements, which are entitled to deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-45 (1984). After considering the very arguments Medtronic raises here, the FDA determined that section 360k(a) "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R. 808.1(d)(2). The FDA explained that it:

> cannot accept the argument that an identical State or local requirement is preempted because it is "in addition to" the FDA requirement. Such an interpretation ... renders meaningless the "different from" language ... because under this theory any State and local requirement would be preempted whether or not it was actually "different from" an FDA requirement.

43 Fed. Reg. at 18663; *accord Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1457 (9th Cir. 1995).

Moreover, the FDA has consistently encouraged enforcement of state device laws that do no more than incorporate federal standards. For instance, the agency ruled that California's GMPs

are not preempted because they simply adopt the federal GMPs. The FDA rejected complaints, identical to those of Medtronic, that "the State *may* interpret or apply the [federal] requirement in a different manner." 45 Fed. Reg. at 67322 (emphasis added); *compare* 21 U.S.C. 360k(a)(state requirement preempted if it "*is* different from, or in addition to" applicable federal requirement)(emphasis added). Similarly, the FDA held that state labeling requirements, general enforcement regulations, and state statutes permitting the seizure and embargo of devices are *not* preempted if the substantive standards under which they are enforced do not differ from federal standards. 45 Fed. Reg. at 67322. And the agency urged the "States [to] assist in enforcing the FDA hearing aid regulations by adopting requirements identical to the FDA requirements." *Id.* at 67327. Given these rulings, which enable the states to remove devices from the market, it is difficult to conceive how the Lohrs' damages claims could be preempted if they are premised on substantive duties consistent with applicable federal requirements.[7]

CONCLUSION

For these reasons and those set forth in the Lohrs' previously-filed briefs, the Court should hold that none of the Lohrs' claims is preempted.

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[7] Medtronic faults 21 C.F.R. 808.1(d)(2) for providing that state laws are not preempted if they are "*substantially* identical" to federal requirements. Med. Resp. Br. 39 n.38. But the FDA has interpreted "different from, or in addition to" in this manner so that it can consider how the state "requirement is interpreted and applied, not merely the literal language of the applicable statute." 43 Fed. Reg. at 18663. This FDA regulation prevents the elevation of form over substance and is certainly a "permissible construction" of section 360k(a). *Chevron*, 467 U.S. at 843.

Respectfully submitted,

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OCTOBER TERM, 1995

MEDTRONIC, INC., PETITIONER

v.

LORA LOHR, ET VIR.

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v.

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ON WRITS OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS/CROSS-PETITIONERS

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QUESTION PRESENTED

Whether 21 U.S.C. 360k(a) preempts the state-law tort claims asserted by respondents/cross-petitioners concerning the allegedly defective medical device manufactured by petitioner.

TABLE OF CONTENTS

	Page
Interest of the United States	1
Statement	2
A. Statutory background	2
B. The present litigation	7
Summary of argument	9
Argument:	
Section 521 of the Federal Food, Drug, and Cosmetic Act does not require summary judgment for Medtronic on the ground that the state-law tort claims asserted by the Lohrs are preempted	11
I. Section 521 of the Act preempts only certain state substantive requirements and does not categorically preempt state tort remedies	11
II. The FDA's clearance of Medtronic's device under Section 510(k) of the Act does not preempt the Lohrs' defective-design claims	19
III. The existence of good manufacturing practices promulgated by the FDA under the Act does not require summary judgment for Medtronic on the defective-manufacture claims	22
IV. The labeling provisions of the Act and implementing regulations do not require summary judgment for Medtronic on the Lohrs' failure-to-warn claims	27
Conclusion	29

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Cases:

Allis-Chalmers Corp. v. Lueck, 471 U.S. 202 (1985)	22
American Airlines, Inc. v. *Wolens*, 115 S. Ct. 817 (1995)	14, 21

Cases—Continued: Page

CSX Transp., Inc. v. *Easterwood*, 113 S. Ct. 1732 (1993) 16, 22
Chevron U.S.A. Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) 9, 27
Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) 15, 16, 22, 27
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Hillsborough County v. *Automated Medical Labs., Inc.*, 471 U.S. 707 (1985) 9, 25
Ingersoll-Rand Co. v. *McClendon*, 498 U.S. 133 (1990) 22
Kennedy v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) 16
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Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 301 *et seq.*:
21 U.S.C. 321(h) 3
21 U.S.C. 331(*l*) 27
21 U.S.C. 333(f)(2)(A) 26
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21 U.S.C. 351 (1976) 2
21 U.S.C. 351(f) 5
21 U.S.C. 351(f)(2)(B) 4
21 U.S.C. 351(h) 24
21 U.S.C. 352 (1976) 2, 3, 5, 27
21 U.S.C. 352(a) 27
21 U.S.C. 352(f) 27

Statutes and regulations—Continued: Page

21 U.S.C. 352(n) 27
21 U.S.C. 352(r) 27
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21 U.S.C. 360c(a)(1)(A) 3
21 U.S.C. 360c(a)(1)(B) 3
21 U.S.C. 360c(a)(1)(C) 3
21 U.S.C. 360c(c)(2)(B) 24
21 U.S.C. 360c(f)(1) 5
21 U.S.C. 360d 3
21 U.S.C. 360e(d)(1)(A)(i) 4, 20
21 U.S.C. 360e(d)(2)(A) 4, 20
21 U.S.C. 360e(d)(2)(B) 20
21 U.S.C. 360e 27
21 U.S.C. 360e(b) 4
21 U.S.C. 360e(c) 4
21 U.S.C. 360e(d) 4
21 U.S.C. 360e(i) 19
21 U.S.C. 360h 5
21 U.S.C. 360j(e) 27
21 U.S.C. 360j(f) 3, 24
21 U.S.C. 360j(f)(2)(C) 24
21 U.S.C. 360j(g) 4, 27
21 U.S.C. 360k (§ 521) 5, 11, 14, 15, 16, 17, 18
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21 U.S.C. 360k(a)(2) 20
21 U.S.C. 360k(b) (§ 521(b)) 2, 6, 13, 18, 19
21 U.S.C. 371(a) 2
21 U.S.C. 374 26
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Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 21 U.S.C. 360c *et seq.* 2
§ 2, 90 Stat. 574 (21 U.S.C. 360k) 1
§ 3, 90 Stat. 575 3
Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 *et seq.* 3, 7

Statutes and regulations—Continued: Page

§ 4(b), 104 Stat. 4515-4517 (21 U.S.C. 360e (i)) 7
§ 5, 104 Stat. 4517-4518 3
§ 12(a), 104 Stat. 4523 (21 U.S.C. 360c(i)(3)(A) 7
28 U.S.C. 1441(b) 8
21 C.F.R.:
Pt. 5:
Section 5.10(a)(1) 2
Pt. 801 ..... 3, 27
Section 801.5 27
Pt. 807:
Section 807.100 19
Section 807.81 21
Section 807.87 5
Section 807.97 20
Pt. 808:
Section 808.1(b) 15
Section 808.1(d) 8
Section 808.1(d)(2) 13
Section 808.1(d)(6) 13
Section 808.20(c)(1) 18
Pt. 812 4
Pt. 814 4
Section 814.44(d) 4
Section 814.45(c) 4
Pt. 820 3
Section 820.20 24
Section 820.25 24
Pt. 821:
Section 821.50 26
Pt. 860:
Section 860.3(c)(1) 3
Pt. 870:
Section 870.3680(b) 7

Regulations—Continued: Page

Pt. 880:
Section 880.6230 3
Pt. 884:
Section 884.5460 3
Section 884.5470 3

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p. 10,688 15
p. 10,689 15
p. 10,693 6
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p. 5850 15
p. 13,779 2
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p. 9186 13
p. 9293 25
p. 30,383 12
pp. 30,383-30,384 25
p. 30,384 12
p. 30,387 12
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59 Fed. Reg. 23,731 (1994) 7
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H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) 2, 14, 15
Joint Hearings on FDA Practice and Procedure Before the Subcomm. on Health of the Comm. on Labor and Public Welfare and the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 94th Cong., 1st Sess. (1975) 16

Miscellaneous—Continued: Page

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S. Rep. No. 33, 94th Cong., 1st Sess. (1975) 2, 15

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In the Supreme Court of the United States

OCTOBER TERM, 1995

No. 95-754

MEDTRONIC, INC., PETITIONER

v.

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No. 95-886

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v.

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ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS/CROSS-PETITIONERS

INTEREST OF THE UNITED STATES

This case concerns the interpretation of Section 521(a) of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 360k(a), a provision added to the Act by the Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 574, to govern the preemption of state and local requirements with respect to medical devices.

The Secretary of Health and Human Services is responsible for administering the Act through the Food and Drug Administration (FDA). 21 U.S.C. 371(a), 393; 21 C.F.R. 5.10(a)(1). The FDA has promulgated regulations that interpret Section 521(a) and implement the substantive provisions of the Medical Device Amendments, and the FDA is authorized to grant exemptions from preemption under Section 521(b) of the Act. Moreover, the FDA's administration of the Act is affected by the extent to which state-law remedies for defective medical devices are available.

STATEMENT

A. Statutory Background.

1. Before 1976, the federal government had quite limited authority over medical devices. See Pet. App. 2a.[1] It consisted primarily in the FDA's authority to take action against adulterated or misbranded devices. See 21 U.S.C. 351, 352 (1976); see also H.R. Rep. No. 853, 94th Cong., 2d Sess. 6 (1976). In 1976, in response to injuries caused by the Dalkon Shield intrauterine device and other medical devices, Congress expanded federal authority over medical devices by enacting the Medical Device Amendments, Pub. L. No. 94-295, 90 Stat. 539 (codified primarily at 21 U.S.C. 360c *et seq.*). See S. Rep. No. 33, 94th Cong., 1st Sess. 1 (1975); H.R. Rep. No. 853, *supra*, at 8; 122 Cong. Rec. 13,779 (1976) (remarks of Rep. Fountain). The Amendments were "intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, *supra*, at 12.

[1] References to "Pet. App." are to the Appendix to the Petition in No. 95-754.

The Amendments required the FDA to classify every medical device in commercial distribution at the time of enactment into one of three categories, depending on the degree of regulation necessary to ensure its safety and effectiveness. See 21 U.S.C. 360c(a).[2] Class I devices, such as tongue depressors, are subject to "general controls." 21 U.S.C. 360c(a)(1)(A); 21 C.F.R. 860.3(c)(1), 21 C.F.R. 880.6230; Pet. App. 4a. General controls relate to, among other matters, the labeling of devices and "good manufacturing practices" (GMPs). 21 U.S.C. 360c(a)(1)(A); see 21 U.S.C. 352, 360j(f), 21 C.F.R. Pts. 801, 820. Class II devices, such as tampons, are subject to both general controls and "special controls." 21 U.S.C. 360c(a)(1)(B); 21 C.F.R. 884.5460, 884.5470. Special controls may include performance standards, which are criteria specifically formulated for a particular type of device. *Ibid.*; 21 U.S.C. 360d.[3]

Class III devices—which include pacemaker leads, the device at issue here—present the greatest potential risk to human health.[4] Consequently, Class III devices are in

[2] The Amendments also revised the statutory definition of "device," but not in ways relevant here. 90 Stat. 575. In general, the term includes, *inter alia*, any item that is intended to affect the structure of any function of the body and that does not rely on chemical action to achieve its intended effect. See 21 U.S.C. 321(h).

[3] The Amendments provided for the development of performance standards for Class II devices. In the Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, 104 Stat. 4511, Congress expanded the range of controls applicable to Class II devices; these "special controls" for Class II devices include, but are no longer limited to, performance standards. SMDA § 5, 104 Stat. 4517-4518; 21 U.S.C. 360c(a)(1)(B).

[4] 21 U.S.C. 360c(a)(1)(C) defines a Class III device as one the safety and effectiveness of which cannot reasonably be assured through general and special controls and that either is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury."

general subject not only to general controls and special controls but also to premarket approval, which the FDA grants if there is reasonable assurance that the specific device that a particular manufacturer seeks to market is safe and effective. 21 U.S.C. 360e(d)(1)(A)(i) and (2)(A); see 21 C.F.R. 814.44(d), 814.45(c).[5] Premarket-approval (PMA) applications must be supported by detailed test data on safety and effectiveness, and the PMA process is extensive for both the device-manufacturer and the FDA. See 21 U.S.C. 360e(c) and (d); 21 C.F.R. Pt. 814.

The Amendments did not require that Class III devices on the market at the time of enactment be withdrawn from the market pending premarket approval. Instead, the Amendments provided that such a device would not be subject to premarket approval until 90 days after the FDA had finally classified it as a Class III device *and* had promulgated a regulation requiring premarket approval for that device. 21 U.S.C. 360e(b), 351(f)(2)(B); see also H.R. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990).

The Amendments also were designed to ensure that the provisions just described did not give manufacturers of pre-Amendments Class III devices a competitive advantage over manufacturers who sought to market similar devices *after* the Amendments were enacted.[6] Thus, a post-Amendment device satisfying the criteria for Class III classification may be marketed without premarket approval if the FDA determines that it is "substantially equivalent" to a pre-Amendments Class III device, and

[5] Class III devices may, however, be approved for investigational use without premarket approval, under an "investigational device exemption[]." 21 U.S.C. 360j(g); see 21 C.F.R. Pt. 812.

[6] See David A. Kessler, et al., *The Federal Regulation of Medical Devices*, 317 New Eng. J. Med. 357, 359 (1987); Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 513 (1988).

thereafter it need not receive premarket approval until premarket approval is required for the pre-Amendments device to which it is substantially equivalent. See 21 U.S.C. 360(k), 360c(f)(1).

The process by which the FDA clears "substantially equivalent" devices for marketing is known either as the "510(k) process" (a name derived from Section 510(k) of the Act, 21 U.S.C. 360(k), upon which the process is based) or as the "premarket notification" process (because Section 510(k) allows such devices, after issuance of an FDA order, to be marketed 90 days after the manufacturer notifies the FDA of its intention to do so). The 510(k) process traditionally has been much less extensive than the PMA process, particularly prior to 1990. See pages 6-7, *infra*; 21 C.F.R. 807.87.[7] It accordingly does not impose a significant competitive disadvantage on the manufacturers of post-Amendments devices relative to the manufacturers of the pre-Amendments Class III devices that are substantially equivalent.

The Amendments did not expressly authorize private actions, but they did give certain remedial powers to the Secretary. See 21 U.S.C. 360h. The Amendments also preserved the Secretary's power to take enforcement action against misbranded or adulterated devices. 21 U.S.C. 351(f), 352.

Finally, the Amendments included the following pre-emption provision, in Section 521(a) of the Act:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

[7] See generally Jonathan S. Kahan, *Premarket Approval versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510 (1984).

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a). Subsection (b) of Section 521 authorizes the Secretary to exempt a state or local requirement from preemption under specified circumstances. 21 U.S.C. 360k(b).

2. "The FDA faced an enormous task in essentially starting from scratch in regulating devices." S. Rep. No. 513, 101st Cong., 2d Sess. 14 (1990).[8] As of 1990, the FDA had promulgated relatively few regulations requiring premarket approval for pre-Amendments Class III devices. See *id.* at 15. In addition, an unexpectedly large proportion (approximately 80%) of Class III devices marketed after 1976 was found "substantially equivalent" to pre-Amendments devices, and therefore did not require premarket approval until such approval was required for the substantially equivalent pre-Amendments Class III devices. H.R. Rep. No. 808, *supra*, 14. As a result, the 510(k) process came to serve a more significant function than simply removing a competitive disadvantage for the manufacturers of certain post-Amendments devices on a temporary basis, until the contemplated PMA regulations were in place. Instead, the vast majority of pre-Amendments Class III devices and substantially equivalent post-Amendments devices, including the device at issue here, were "effectively grandfathered from the regulation appropriate to their classification." S. Rep. No. 513, *supra*, at 15; see also Subcommittee on Oversight and Investigations of the House Comm. on Energy and Commerce, 98th Cong., 1st Sess., *Medical Device Regulation: The FDA's Neglected Child* 13-14, 18-21 (Comm. Print 98-F 1983).

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[8] There were estimated to be 1500 companies producing 12,000 types of medical devices at the time of enactment. 121 Cong. Rec. 10,693 (1975) (remarks of Sen. Ribicoff).

3. In light of the experience under the 1976 Amendments, Congress enacted the Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, 104 Stat. 4511. The SMDA, among other things, required 510(k) submissions to include a summary of information on the safety and effectiveness of the device. See SMDA § 12 (a), 104 Stat. 4523 (21 U.S.C. 360c(i)(3)(A)). The SMDA also required the FDA, by December 1, 1995, to publish, for each pre-Amendments Class III device, a regulation that either reclassified the device or retained it in Class III. SMDA § 4(b), 104 Stat. 4515-4517 (21 U.S.C. 360e(ii)). That process is still underway. See 59 Fed. Reg. 23,731 (1994).

B. The Present Litigation.

1. The device at issue here is a pacemaker lead, a Class III device that conducts electrical impulses from a pulse generator to the heart. Pet. App. 6a; see 21 C.F.R. 870.3680(b). Medtronic received FDA clearance under Section 510(k) to market its Model 4011 pacemaker lead as a "substantially equivalent" device in 1982. As such, the Model 4011 is subject to the general controls applicable to all medical devices, but it was not required to receive premarket approval before entering the market.

2. A Model 4011 was implanted in Ms. Lohr in 1987. In 1990, it suddenly failed, requiring her to have emergency surgery. Pet. App. 6a. In 1993, Ms. Lohr and her husband filed this action for damages against Medtronic in Florida state court. Relying on Florida law, they sought to recover on the theories that the device was negligently designed and manufactured; that Medtronic breached a duty to warn the Lohrs of the Model 4011's tendency to fail suddenly; and that, because the device was defective and unreasonably dangerous to foreseeable users "[a]t the time of the design, manufacture, sale and

implantation," Medtronic was strictly liable for the defect. C.A. R.E. 8-9.[9]

Medtronic removed the suit to the federal court on diversity grounds. See 28 U.S.C. 1441(b). Medtronic later moved for summary judgment, arguing that all of the Lohrs' claims are preempted by Section 521(a) of the Act. The district court granted the motion. Pet. App. 1b-3b.

3. The court of appeals affirmed in part and reversed in part. Pet. App. 1a-36a. It held that Section 521(a) preempts the negligent-manufacture claim, the failure-to-warn claim, and the strict-liability claim to the extent it is based on defective manufacturing or labeling. *Id.* at 29a-36a. But the court held that Section 521(a) does not preempt the negligent-design claim or the strict-liability claim to the extent that it is based on defective design. *Id.* at 24a-29a.

As an initial matter, the court of appeals held that state common law applied in tort actions may constitute a "requirement" within the meaning of Section 521(a), and therefore may be subject to preemption. Pet. App. 11a-14a. The court regarded that holding to be compelled by its prior decision in *Duncan* v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994). Pet. App. 11a.

Next, the court of appeals considered the meaning of the term "requirement" as that term is used in Section 521(a) to refer to the federal provisions that have preemptive force. The court found that term ambiguous and accordingly turned to the FDA's regulation on the subject, which provides in relevant part (21 C.F.R. 808.1 (d)):

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act.

[9] The Lohrs also claimed a breach of the implied warranty of fitness and merchantability imposed by state law, but that claim was dismissed and is not at issue in this Court. See Pet. App. 6a n.3.

The court determined that the regulation reflects a reasonable interpretation of Section 521(a) and is therefore entitled to deference. Pet. App. 17a (citing *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984)); see also Pet. App. 15a (citing *Hillsborough County* v. *Automated Medical Labs., Inc.*, 471 U.S. 707, 712-714 (1985)).

The court of appeals understood the FDA's regulation to mean that "preemption-triggering requirements should, in some way, be 'restricted by nature' to a particular process, procedure, or device." Pet. App. 21a-22a (footnote omitted). Based on that understanding, the court held that the defective-manufacture claims are preempted by the good manufacturing practices (GMPs) promulgated by the FDA under the Medical Device Amendments, and that the failure-to-warn claims are preempted by the labeling provisions of the Amendments and implementing regulations. *Id.* at 31a, 33a.

The court of appeals held that Section 521(a) does not preempt the defective-design claims because the Amendments do not require any particular design for the Model 4011. Pet. App. 25a-29a. The court rejected Medtronic's argument that the FDA's clearance of the device under Section 510(k) constitutes a "requirement" that preempts tort claims implicating the device's safety or effectiveness. Pet. App. 27a. The court determined that 510(k) clearance does not reflect "a finding of safety and effectiveness." *Ibid.*

SUMMARY OF ARGUMENT

I. Section 521(a) of the Act does not categorically preempt state tort remedies. Section 521(a) preempts certain state "requirement[s]." The FDA has consistently, and reasonably, construed the term "requirement" to refer

to substantive, but not remedial, provisions. Applying that approach here, a substantive obligation created by state tort law, such as the duty to use due care, may constitute a "requirement" within the meaning of Section 521(a); but that term does not encompass a state tort principle entitling a plaintiff to recover damages for the defendant's breach of a substantive common-law obligation.

II. The court of appeals correctly held that the FDA's clearance of petitioner's device under Section 510(k) of the Act does not preempt the defective-design claims. The clearance of a post-Amendments Class III device under Section 510(k) reflects a determination that the device is "substantially equivalent" to a pre-Amendments device and therefore may be legally marketed, rather than an independent determination that the device is safely designed. Since the FDA will not have determined the safety and effectiveness of the pre-Amendments device, the "substantial equivalence" determination is not tantamount to a determination of safety and effectiveness, much less a determination that a particular design is required by the Act.

III. The court of appeals erred in holding that the "good manufacturing practices" (GMPs) promulgated by the FDA preempt the defective-manufacture claims. The court of appeals reasoned that, because the GMPs address "almost every aspect of the manufacturing process," a jury's determination that some aspect of the manufacture of petitioner's device was inadequate "could" impose a requirement that was different from, or in addition to, the requirements imposed by the GMPs. But Section 521(a) conditions preemption on a determination that the particular state requirement on which the plaintiff relies "*is* different from, or in addition to," a federal requirement. The mere possibility that state law might diverge in some respects is insufficient. The court of appeals did not specifically identify any GMP requirement from which a jury determination in this case would necessarily depart.

IV. The court of appeals also erred in holding that the labeling provisions of the Act and implementing regulations preempt the failure-to-warn claims. As an initial matter, while the Act and its regulations address the labeling of devices, they generally do not prescribe requirements for advertising or other modes of communication. Thus, the failure-to-warn claims are not preempted insofar as they concern modes of communication other than labeling. Nor are they preempted insofar as they concern labeling. The Act and regulations for the most part address the labeling of devices only in generalized terms. A jury's determination that a particular device was inadequately labeled would not necessarily be based on any common-law requirement "different from, or in addition to," those general labeling provisions under federal law.

ARGUMENT

SECTION 521 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DOES NOT REQUIRE SUMMARY JUDGMENT FOR MEDTRONIC ON THE GROUND THAT THE STATE-LAW TORT CLAIMS ASSERTED BY THE LOHRS ARE PREEMPTED

I. Section 521 Of The Act Preempts Only Certain State Substantive Requirements And Does Not Categorically Preempt State Tort Remedies

Section 521 of the Food, Drug and Cosmetic Act (FDCA or Act) does not categorically preempt state tort remedies, or any other form of state-created remedies, as applied to persons who manufacture and sell defective medical devices. Section 521 preempts certain state "requirement[s]" regarding such devices. 21 U.S.C. 360k(a). The FDA has consistently interpreted that term to refer to substantive, rather than remedial, state provisions. A substantive common-law obligation, such as the duty

to use due care, may constitute a "requirement" under Section 521(a), just as a substantive statutory obligation may do so. But the term "requirement" does not encompass the judicially created principle that allows a plaintiff to recover damages for the defendant's violation of a substantive common-law obligation.

A. The FDA's view that Section 521(a) does not preempt state remedies, as such, is clear from regulations and advisory rulings providing that a State may use state-created remedies to enforce state substantive requirements for medical devices, if those substantive requirements are substantially identical to federal substantive standards. In that situation, preemption does not occur under Section 521(a) because the state substantive "requirement[s]" are not "different from, or in addition to," federal requirements applicable under the FDCA.

The FDA took that view in June 1977, when it proposed regulations interpreting Section 521(a). 42 Fed. Reg. 30,383. In the preamble to the proposed regulations, the FDA stated (*id.* at 30,384):

> Section 521(a), by its terms, applies only to those State or local requirements that are "different from, or in addition to" FDA requirements. Accordingly, * * * the Commissioner concluded that the provision does not preempt those State or local requirements that are equal to or substantially identical to FDA requirements.

The FDA further stated in the preamble that Section 521(a) does not preempt "general State or local law provisions governing the enforcement of requirements applicable to medical devices," because "[s]uch general enforcement provisions are not themselves requirements." *Ibid.* The proposed regulations incorporated that position. See *id.* at 30,387.[10] The relevant regulatory provisions

[10] The FDA had previously taken the same view in February 1977, when it published a proposed ruling on California's application to have certain state statutory provisions applicable to medical devices exempted from preemption under Section 521(b). 42 Fed. Reg. 9186 (1977).

were adopted as final regulations and remain unchanged in relevant part. 21 C.F.R. 808.1(d)(2) and (6).

The FDA has made clear that the state "enforcement provisions" that it considers not to constitute "requirement[s]" include *judicial* remedies sought by private parties to enforce state substantive requirements. In an advisory opinion issued in 1984, the FDA stated that Section 521(a) "does not preempt the application of State law injunctive remedies" to pre-Amendments intrauterine contraceptive devices, because "[r]ules or requirements established by States to govern the legal remedies available under the State judicial system are not 'requirements with respect to a device' within the meaning of section 521(a) of the act." Resp./Cross-Pet. Br. App. 13a. Although the advisory opinion dealt with injunctive remedies, its conclusion fully applies to damage remedies in a tort action. Moreover, tort remedies are reasonably characterized as "enforcement provisions" within the meaning of the FDA's regulation interpreting Section 521(a), because they enable a plaintiff to enforce a substantive duty imposed upon the defendant by the State's common law.

B. The FDA's interpretation of Section 521(a) not to preempt state tort remedies accords with the text of Section 521(a), as well as its legislative history and purpose. Section 521(a) provides that no State "may establish or continue in effect with respect to a device * * * any requirement" that (1) "is different from, or in addition to," any requirement applicable under the FDCA, and (2) relates to the safety and effectiveness of the device or other matters included in a requirement applicable to the device under the FDCA. 21 U.S.C. 360k(a). The term "requirement" in that context is most naturally read

to refer to the attributes of a device itself or to substantive duties imposed on persons who manufacture or sell it, rather than to remedial provisions. See *Webster's Third New International Dictionary* 1929 (1986) ("requirement," def. b: "something called for or demanded: a requisite or essential condition"). That interpretation is consistent with the well-established distinction between rights or duties, on the one hand, and remedies or other means for enforcing rights or duties, on the other hand. Cf. *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817, 824 (1995) (distinguishing, for preemption purposes, between state-law action based on violation of "state-imposed obligations," and state-law action to remedy violation of "privately ordered obligations").

Moreover, the legislative history of the 1976 Amendments indicates that Congress intended Section 521 to protect the manufacturers of medical devices from conflicting substantive requirements. See H.R. Rep. No. 853, *supra*, at 45 (preemption provision covers statutes providing for inconsistent "regulation" of devices). By contrast, nothing in the legislative history suggests that Congress also intended to shield manufacturers from state-created remedies for violations of state substantive requirements that were not "different from, or in addition to," federal substantive requirements. The legislative history also reflects Congress's recognition that, even after the Amendments were fully implemented, "no regulatory mechanism can guarantee that a product will never cause injury." H.R. Rep. No. 853, *supra*, at 16. Yet the legislative history contains no evidence that Congress intended to eliminate state tort remedies even for those injuries that are attributable to *defective* devices, especially ones marketed *before* the Amendments were fully implemented through the promulgation of regulations mandating premarket approval for those devices. That silence is significant in light of Congress's specific awareness of the numerous personal injuries caused by the

Dalkon Shield.[11] Cf. *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Against this background, FDA has reasonably interpreted the term "requirement" in Section 521(a) not to preempt state tort remedies or other state remedial provisions. Analysis under Section 521 should therefore focus on the state substantive provisions invoked by the Lohrs to support an award of damages and the federal substantive provisions invoked by Medtronic to defeat such an award.

C. The distinction between substantive and remedial provisions is not the same as the distinction between substantive obligations imposed by common law and substantive obligations imposed by positive enactments, such as statutes and regulations. The Lohrs rely on the latter distinction to argue that the term "requirement" in Section 521(a) does not preempt any state tort claims concerning defective medical devices. Resp./Cross-Pet. Br. 16-34. That argument, in our view, is difficult to square with *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 527-529 (1992).[12]

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[11] S. Rep. No. 33, *supra*, at 1; H.R. Rep. No. 853, *supra*, at 8; 121 Cong. Rec. 10,688 (1975) (remarks of Sen. Kennedy); *id.* at 10,689 (remarks of Sen. Nelson); 122 Cong. Rec. 5850 (1976) (remarks of Rep. Abzug); see also *Joint Hearings on FDA Practice and Procedure Before the Subcomm. on Health of the Comm. on Labor and Public Welfare and the Subcomm. on Admin. Practice and Procedure of the Senate Comm. on the Judiciary*, 94th Cong., 1st Sess. 47 (1975).

[12] The FDA has not heretofore taken a formal position specifically on whether the term "requirement" in Section 521(a) encompasses obligations established by a State's common law of torts. However, the FDA regulations interpreting Section 521(a) do describe it as preventing States from establishing or continuing in effect "any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*)." 21 C.F.R. 808.1(b) (emphasis added)). It has been suggested that the term "court decision" could be read to refer to a decision construing

In *Cipollone*, this Court held that a failure-to-warn claim against a cigarette company was preempted by a federal provision that stated: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 505 U.S. at 515 (quoting statute). The Court rejected the plaintiff's argument that "common-law damages actions do not impose 'requirement[s] or prohibition[s].'" *Id.* at 521. The plurality concluded that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law," *ibid.*; see generally *id.* at 521-523, and the separate opinion of Justice Scalia, joined by Justice Thomas, specifically agreed with that conclusion, *id.* at 548-549. See also *CSX Transp., Inc.* v. *Easterwood*, 113 S. Ct. 1732, 1737-1738 (1993); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959).

The Lohrs contend that *Cipollone* is distinguishable. Resp./Cross-Pet. Br. 18-19, 24-25. They rely on three features of the text of Section 521. In our view, none of those features suffices to distinguish *Cipollone*.

First, subsection (a) of Section 521 uses the term "requirement" to refer to both the state provisions that are subject to preemption and the federal provisions that have preemptive force. The Lohrs point out that the federal "requirement[s]" are imposed solely by positive enact-

a statute, regulation, or ordinance, and not to a decision applying the common law. See *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453, 1461-1462 (9th Cir. 1995) (Reinhardt, J., concurring); Resp./Cross-Pet. Br. 26 n.7. We are not aware of any contemporaneous agency materials that so confines the regulation's reference to "any requirement having the force and effect of law * * * established by * * * court decision." The Lohrs cite a 1987 letter from an FDA official in support of their position (see Resp./Cross-Pet. Br. 23 n.5, App. 14a), but that letter was not a formal advisory opinion, its import is unclear, and it contains no legal reasoning.

ments: the FDCA and implementing regulations. They reason that the state "requirement[s]" should also be limited to positive enactments, and therefore exclude standards developed and applied at common law. Resp./Cross-Pet. Br. 18-19.

The problem with that reasoning is that the limitation on the type of federal provisions that have preemptive force is not attributable to the term "requirement." It is, instead, attributable to the words that modify "requirement." A state provision may be preempted only by a federal requirement "applicable under this chapter." 21 U.S.C. 360k(a). It is the latter phrase that limits the federal provisions having preemptive force to those imposed by the FDCA and implementing regulations, rather than by common law.

Second, Section 521(a) bars a State from "establish-[ing] or continu[ing] in effect *with respect to a device*" certain state requirements. 21 U.S.C. 360k (emphasis added). The Lohrs argue that the "with respect to" phrase limits the scope of the provision to state requirements that specifically refer or relate to medical devices, and therefore excludes general common-law duties. Resp./Cross-Pet. Br. 19-21.

That argument is strained as a grammatical matter. Section 521(a) provides in relevant part that no State "may establish or continue in effect *with respect to a device intended for human use* any requirement * * * which is different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. 360k(a) (emphasis added). The Lohrs read the italicized phrase as modifying "requirement"; thus, they assert a "contrast between positive-law requirements 'with respect to a device' and general common-law duties." Resp./Cross-Pet. Br. 20. But the "with respect to" phrase cannot modify the word "requirement," because "requirement" comes *after* that phrase. Rather, the phrase modifies the words ("establish or continue to effect") that

come immediately *before* it. The phrase indicates that, if a state requirement meets the conditions for preemption, the State cannot establish or continue that requirement in effect "with respect to a device." The phrase thus preserves the authority of a State to have the requirement in effect insofar as it applies to things *other* than medical devices. By allowing in this manner for partial preemption of state "requirement[s]," the "with respect to" clause suggests that such a "requirement" may be one of general applicability. Cf. *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992).

Third, subsection (b) of Section 521 allows the FDA to exempt state "requirement[s]" from preemption under subsection (a). The Lohrs assert that it would be difficult for a State to seek an exemption for a common-law "requirement" developed or applied in judicial decisions. Resp./Cross-Pet. Br. 24. Based on that assertion, they argue that subsection (b) contemplates that the state "requirement[s]" for which an exemption will be sought are ones imposed by positive enactments, such as state statutes and administrative regulations, and that the "requirement[s]" that would otherwise be subject to preemption under subsection (a) should be limited in the same manner.

Although it may be difficult, as a practical matter, for a State to request an exemption for a common-law "requirement," such a request is not legally barred on the face of subsection (b).[13] Moreover, respondents/cross-petitioners assume that Congress intended to ensure the availability of an exemption under subsection (b) for

[13] The FDA's regulations do not expressly contemplate exemptions for State "requirement[s]" imposed in judicial decisions applying common-law principles. See 21 C.F.R. 808.20(c)(1) (State or locality must identify and provide current copy of the "statute, rule, regulation, or ordinance" for which it seeks an exemption). The FDA has not, however, taken the position that Section 521(b) renders such exemptions unavailable, and the FDA does not do so here.

every type of "requirement" that is subject to preemption under subsection (a). That assumption is not compelled by the text of the statute. Subsection (b) states that the Secretary "may" grant an exemption; it does not say that she "must" do so. Moreover, Congress might well have contemplated that the Secretary would decide, in her discretion, to grant exemptions chiefly for statutory and administrative "requirement[s]," rather than for "requirement[s]" developed in the course of case-by-case adjudication at common law, because judicial decisions are more numerous and their meaning and precedential effect are sometimes unclear.

II. The FDA's Clearance Of Medtronic's Device Under Section 510(k) Of The Act Does Not Preempt The Lohrs' Defective-Design Claims

The court of appeals correctly held that Section 521(a) does not preempt the Lohrs' claims regarding the design of the Model 4011. Pet. App. 24a-29a (negligence claim concerning design), 35a (strict liability claim concerning design). Medtronic bases its argument to the contrary on the fact that the FDA cleared the Model 4011 under Section 510(k) of the Act, 21 U.S.C. 360(k), as a substantially equivalent device. That argument reflects a misunderstanding of the 510(k) process.

The clearance of a post-Amendments device under Section 510(k)—based on a determination that the device is substantially equivalent to a pre-Amendments Class III device—does not reflect a determination by the FDA that the device is safe and effective, much less a specific determination that the device's design is required to ensure its safety and effectiveness. "[A] determination of substantial equivalence * * * is not equivalent to an approval by the FDA of the device's safety and effectiveness." H.R. Rep. No. 808, *supra*, at 14; see 21 U.S.C. 360e(i); 21 C.F.R. 807.100. As the court of appeals observed, the FDA ordinarily will not have determined whether the

pre-Amendments device was safe and effective (since the FDA lacked the general authority to do so prior to enactment of the Amendments). Pet. App. 26a. Accordingly, FDA regulations specify that a substantial equivalence determination "does not in any way denote official approval of the device," and that any representation conveying "an impression of official approval * * * is misleading and constitutes misbranding." 21 C.F.R. 807.97.

A "substantial equivalence" determination differs in this respect from premarket approval, which is required for other post-Amendments devices that are classified in Class III. As explained above, the FDA may not approve a PMA application without "a showing of reasonable assurance" that the device is "safe" and "effective" for "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. 360e(d)(1)(A)(i) and (2)(A)-(B).[14]

There is an additional reason why the defective-design claims would not be preempted by a substantial equivalence determination, even if it were deemed tantamount to the determination of safety and effectiveness required for premarket approval. Neither the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of a device originates with its manufacturer. Even if design specifications could be characterized as "requirement[s]" in some sense, once the FDA clears the device under Section 510(k), they are not "requirement[s] *applicable* to the device *under th*[*e Act*]." 21 U.S.C. 360k(a)(2) (emphasis added); see also 21 U.S.C. 360k(a)(1). Instead, the specifications are applicable to the device as a result of the voluntary decision of a private party, the manufacturer, to introduce the device into the market with a design of the manufacturer's choosing.

[14] There is no occasion in this case to consider the extent to which the PMA process may result in requirements applicable to a device under the FDCA that would trigger preemption under Section 521(a).

That federal law attaches a consequence to such private decisions does not convert them into federal "requirements." Cf. *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. at 824.

Medtronic argues (Pet. Br. 44-45) that the defective-design claims are preempted because the manufacturer of a "substantially equivalent" device must obtain FDA clearance before it can change the design of the device. FDA clearance is also required, however, when the manufacturer of a pre-Amendments Class III device seeks to change its design. 21 C.F.R. 807.81. In the absence of a design change (or the promulgation of a PMA regulation for the device), the marketing of such a device will never have been cleared (much less approved) by the FDA. In light of that fact, no one could plausibly argue that defective-design claims regarding pre-Amendments Class III devices are preempted.[15] Congress enacted the Medical Device Amendments to increase protection against defective devices. If Section 521(a) preempted claims regarding devices that were not even subject to regulation under the Amendments, the Amendments would have *decreased* the level of protection. Thus, a defective-design claim concerning a device (whether pre- or post-Amendments) is not preempted merely because the FDA must clear certain changes in the device's design.

[15] Although Medtronic does not advance that argument in this Court, it did advance the argument below, and the court of appeals correctly rejected it. Pet. App. 27a-29a. As the court reasoned, construing Section 521(a) to bar tort claims against manufacturers of pre-Amendments devices would accord a benefit "to devices that never paid the [Amendments'] regulatory 'price' for market entry." Pet. App. 28a. At the same time, the court recognized that allowing such claims "would not disturb a manufacturer's developmental calculus because presumably, when such devices were first introduced, the devices were considered a wise business investment despite state-imposed tort liability." *Ibid.* The result of preemption therefore would be to give the manufacturers of pre-Amendments devices "a regulatory windfall." *Ibid.*

III. The Existence Of Good Manufacturing Practices Promulgated By The FDA Under The Act Does Not Require Summary Judgment For Medtronic On The Lohrs' Defective-Manufacture Claims

The court of appeals erred in holding that the Lohrs' defective-manufacture claims necessarily are preempted by Section 521(a) of the Act. Pet. App. 29a-31a (negligence claim regarding manufacture), 35a (strict liability claim regarding manufacture). The court determined that the common law on which those claims are based "constitutes * * * state requirement[s] 'different from, or in addition to' the GMP regulations' specific manufacturing requirements." *Id.* at 31a; see also *id.* at 35a. That determination rests on an inadequate analysis of the "different from, or in addition to" condition for preemption under Section 521(a). 21 U.S.C. 360k(a)(1).[16]

By virtue of the "different from, or in addition to," limitation, it is necessary to compare the state requirement that is assertedly preempted to the federal requirement that assertedly preempts it. When the state requirement is asserted to be general state common-law principles applied in tort actions, the court must focus on the specific claim, rather than general principles.[17] Similarly,

[16] The court of appeals based its preemption holding regarding the defective-manufacture claims solely on the GMPs. The court rejected Medtronic's argument that those claims are barred as a result of the FDA's 510(k) clearance of the Model 4011. Pet. App. 30a. The court's rejection of the 510(k) argument was correct for reasons discussed in Section II, *supra*, pp. 19-21. In any event, FDA clearance of a model under Section 510(k) does not signify a determination by the FDA that the particular device purchased by the plaintiff was properly manufactured.

[17] See *CSX Transp.*, 113 S. Ct. at 1738, 1742-1743; *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 45-48 (1987); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 209 (1985); see also *Morales*, 504 U.S. at 386; *Cipollone*, 505 U.S. at 553-554 (Scalia, J., concurring in part and dissenting in part); cf. *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 138-142 (1990).

the court must identify the particular federal requirement that, the defendant contends, has preemptive force. Only then can the court decide whether the imposition of liability based on the plaintiff's claim would be based on a requirement that is actually "different from, or in addition to," a federal requirement.[18]

The court of appeals failed to undertake that analysis with the necessary precision. The court reasoned that the defective-manufacture claims invited a jury to decide how the Model 4011 should have been built, and that the jury's decision "*could* create a standard of conduct 'different from, or in addition to' " the GMPs. Pet. App. 30a (emphasis added). The court did not, however, identify any GMP from which a jury verdict in favor of the Lohrs would necessarily depart. It merely observed that "the GMP regulations create standards for almost every aspect of the manufacturing process." *Id.* at 31a. At the same time, the court recognized that those regulations "are written in necessarily broad language." *Ibid.* Thus, the court based its preemption holding on the mere possibility that a tort plaintiff's defective-manufacture claim might, if successful, effectively be based on a requirement that a device manufacturer do something "different from, or in addition to," something required by the general standards enunciated in the GMPs. Under Section 521(a), however, a state requirement is preempted only if it "*is* different from, or in addition to," a federal requirement. 21 U.S.C. 360k(a)(1) (emphasis added). The Lohrs have not alleged violations of state common-law standards governing defective manufacture that are different from, or in addition to, the applicable GMPs or any other federal requirements. The court of appeals therefore erred in affirming summary judgment for Medtronic on the defective-manufacture claims.

[18] The Secretary, in her discretion, may specify in a regulation or an order approving the marketing of a device what requirements are and are not applicable to the device under the FDCA.

Beyond identifying the error in the court of appeals' analysis, this Court need not essay a comprehensive delineation of the circumstances in which defective-manufacture claims may be preempted by the GMPs. We believe, however, that, for the most part, the GMPs, standing alone, are formulated in terms that are sufficiently general that it would be difficult for a defendant-manufacturer to show that the standard of care applied by the court in a particular case under state common law is "different from, or in addition to," requirements imposed by the GMPs.[19]

To illustrate the point, suppose that the plaintiff alleges that the head of the defendant-manufacturer's quality assurance (QA) program failed second grade and never returned to school, and that the defendant was negligent in hiring that person. There would be no basis for a court to conclude that liability based on that allegation would require anything "different from, or in addition to," the GMPs' requirements. 21 U.S.C. 360k(a)(1). The GMPs broadly require manufacturers to have QA programs and "sufficient personnel with the necessary education, background, training, and experience to assure that all operations are correctly performed." 21 C.F.R. 820.20, 820.25. Application of those general standards necessarily depends on the circumstances under which a particular device was manufactured. It is exceedingly doubtful, however, that the FDA, in applying that general standard, would consider a second-grade education sufficient for the head of a QA program. By the same token,

[19] Our belief that GMPs ordinarily will not found to preempt state tort claims is based on the "different from, or in addition to," condition for preemption in Section 521(a). We do not dispute that the GMPs impose "requirement[s]" within the meaning of Section 521(a). See 21 U.S.C. 333(f)(1)(B)(i) (referring to Section 360j(f), under which GMPs are promulgated, as imposing "requirements"); 21 U.S.C. 351(h) (same); 21 U.S.C. 360c(c)(2)(B) (same); 21 U.S.C. 360j(f)(2)(C) (same).

the court in a common-law tort suit would not be obligated to conclude, based only on the general standards in the GMPs, that the "different from, or in addition to" condition for preemption of a common-law standard of care had been met. In such a case, involving general federal requirements and general duties under state tort law, the court should invoke the presumption against preemption (see *Hillsborough County* v. *Automated Medical Labs., Inc.*, 471 U.S. 707, 715 (1985)) and conclude that the common-law standard of care, as asserted in the plaintiff's claim, is not preempted.[20]

We note that FDA employees periodically inspect device manufacturers for compliance with the GMPs. See

[20] It does not necessarily follow that a State could, by statute or regulation, adopt a rule requiring all medical-device manufacturers to have their QA programs headed by someone with at least a college degree. It could be argued that such a rule would be preempted by the GMPs, quoted in the text, regarding QA programs and personnel. The generalized nature of those GMPs could reflect a judgment by FDA that personnel qualifications should be assessed on a case-by-case basis. If so, a State would contravene FDA's judgment by adopting a uniform rule. A similar conflict in regulatory approach does not necessarily arise when a properly instructed jury finds that the lack of a college degree rendered a particular employee inadequately educated and, on the basis of that finding, imposes civil liability under general principles of state tort law. A generalized GMP on the same subject contemplates that adequacy will be determined on a case-by-case basis.

To consider a further variation, suppose that the FDA adopted a GMP requiring the heads of medical-device QA programs to have high school diplomas. That GMP would, in the absence of an exemption, preempt both state regulations requiring QA heads to have college degrees and a state common-law standard of care requiring that result in a particular case. Cf. 42 Fed. Reg. 9293 (1977) (FDA regulations prescribing requirements for labeling and conditions of sale of hearing aids preempted state requirements with respect to safety and effectiveness of hearing aids); *id.* at 30,383-30,384; 45 Fed. Reg. 67,329 (1980) (FDA declines to grant exemption for state provisions requiring audiological examinations before sale of hearing aids).

21 C.F.R. 821.50; see also 21 U.S.C. 374. Those employees may determine that a particular manufacturer has violated a GMP. Such a determination of noncompliance (or a formal administrative order to the same effect) would not, of course, bar a tort plaintiff's claim that the same conduct by the same manufacturer also violated state common-law standards that were consistent with the GMPs. Tort liability in those circumstances would not rest on any state-law requirement that was "different from, or in addition to," that required by the GMPs. But cf. *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25, 27-30 (1st Cir. 1995).

Moreover, a determination by an FDA inspector that a particular aspect of a manufacturer's operations *complied* with the GMPs would not be sufficiently formal to bar a private tort action alleging negligence in the same aspect of operations. Even if we assume, *arguendo*, that some individualized determinations by FDA could have such preemptive force (by giving content in a particular context to the general standards in the GMPs), it would, in our view, be only those determinations having the same attributes necessary for an agency decision to have preclusive effect under res judicata principles. See, *e.g.*, *United States* v. *Utah Constr. & Mining Co.*, 384 U.S. 394, 422 (1966). Informal agency determinations that lack at least those attributes are of a different character from statutes and regulations, and it is therefore doubtful that Congress intended them to constitute (or embody) "requirement[s]" within the meaning of Section 521(a).[21] Of course, an FDA rule or order that lacks preemptive force may still inform a court's preemption analysis by

[21] Under 21 U.S.C. 333(f)(2)(A), the FDA may assess civil penalties for serious violations of the GMPs "by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5." Such orders, once final, are presumably entitled to preclusive effect under the doctrine of administrative res judicata.

interpreting the substance of federal statutory or regulatory requirements. See *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984).

IV. The Labeling Provisions Of The Act And Implementing Regulations Do Not Require Summary Judgment For Medtronic On The Lohrs' Failure-To-Warn Claims

The Act authorizes the FDA to adopt requirements for the labeling of devices, but it does not prescribe advertising requirements for the device at issue. See 21 U.S.C. 352.[22] Accordingly, the Lohrs' failure-to-warn claims are not preempted insofar as they allege that warnings should have been made through modes of communication other than labeling. Cf. *Cipollone*, 505 U.S. at 527-529 (plurality opinion) (concluding that state-law failure-to warn claims were not preempted insofar as they concerned channels of communication other than advertising or promotion).

Nor was summary judgment for Medtronic warranted on the failure-to-warn claims insofar as they concern the labeling of the Model 4011. In addressing the labeling of devices, the Act and its regulations for the most part speak in general terms. The Act forbids labeling that "is false or misleading," 21 U.S.C. 352(a), and requires the label to contain certain information, including "adequate directions for use," 21 U.S.C. 352(f). The regulations flesh out the meaning of "adequate directions for use" and other statutory requirements. 21 C.F.R. 801.5; see generally 21 C.F.R. Pt. 801. Neither the Act nor the regulations, however, specifically address whether Med-

[22] The FDA may regulate the advertising of prescription drugs, 21 U.S.C. 352(n), and "restricted" devices, 21 U.S.C. 352(r), 360j(e). See also 21 U.S.C. 331(*l*) (prohibiting representation or suggestion in labeling or advertising that device is approved under 21 U.S.C. 360e or 360j(g)).

tronic was required to disclose on its labels the alleged tendency of its pacemaker lead to fail.

In these circumstances, the federal labeling provisions do not, standing alone, preempt the failure-to-warn claims. The success of those claims depends on a jury determination, under instructions consistent with the federal labeling requirements, that the labeling of Medtronic's device was inadequate. We cannot say that such a determination would of necessity rest on any common-law duty of care that is "different from, or in addition to," (21 U.S.C. 360k(a)(1)) the Act's labeling provisions. It is possible that the FDA, applying the federal labeling provisions, could likewise determine that the labeling of Medtronic's device was inadequate.

The FDA's clearance of Medtronic's pacemaker lead under Section 510(k) as a device substantially equivalent to a pre-Amendments Class III device did not reflect a determination that the labeling of that device was a complete recitation of the device's risks and benefits. This is because the underlying testing needed to produce that information had been deferred under the statutory scheme calling for premarket approval for pre-Amendments Class III devices. Just as 510(k) clearance of a device found to be substantially equivalent to a pre-Amendments Class III device does not constitute a federal determination that the device is properly designed or manufactured, it does not constitute a federal determination that the device is adequately labeled for all purposes.

CONCLUSION

The judgment of the court of appeals should be affirmed insofar as the court held that Section 521(a) does not preempt the defective-design claims advanced by respondents/cross-petitioners and reversed insofar as the court held that Section 521(a) of the Act does preempt the defective-manufacture and failure-to-warn claims advanced by respondents/cross-petitioners, and the case should be remanded to the district court for further proceedings on all of those claims.

Respectfully submitted.

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OCTOBER TERM, 1995

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v.
LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit

**Brief for Amicus Curiae,
Plaintiffs' Legal Committee in MDL Docket No. 1014,
in Support of Cross-Petitioners,
Lora Lohr and Michael Lohr**

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TABLE OF CONTENTS

		Page
I.	INTEREST OF AMICUS CURIAE	1
II.	SUMMARY OF THE ARGUMENT	2
III.	ARGUMENT	3
	A. General Principles of Federal Preemption Analysis	3
	B. Application of General Preemption Principles Requires the Conclusion That State Laws of General Applicability, Including the Common Law and Most Products Liability Laws, Are Not Preempted by Federal Law Governing Medical Devices	7
	C. Claims Arising From Conduct That Violates the Federal Medical Device Law Are Not Preempted	17
IV.	CONCLUSION	23

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American Airlines, Inc. v. Wolens, ___ U.S. ___, 115 S. Ct. 817 (1995)	18
Babbitt v. Sweet Home Chapter of Communities for a Great Oregon, ___ U.S. ___, 115 S. Ct. 2407 (1995)	*passim*
Bailey v. Johnson, 48 F.3d 965 (6th Cir. 1995)	9
Berkovitz v. United States, 486 U.S. 531 (1988)	6 n.1
Bowels v. Seminole Rock & Sand Co., 325 U.S. 410 (1945)	5, 19
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English v. General Electric Co., 496 U.S. 72 (1990)	4
Evraets v. Intermedics Intraocular, Inc., 29 Cal.App. 4th 779, 34 Cal.Rptr. 2d 852 (1994)	21
Freightliner Corp. v. Myrick, ___ U.S. ___, 115 S. Ct. 1483 (1995)	4
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Hines v. Davidowitz, 312 U.S. 52 (1941)	4
Jones v. Rath Packing Co., 430 U.S. 519 (1977)	4
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Macky v. Lanier Collection Agency & Service, Inc., 486 U.S. 825 (1988)	6, 18
MacGillivray v. Lederle Laboratories, 667 F. Supp. 743 (D.N.M. 1987)	14
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Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989) 17

Mulligan v. Pfizer, Inc., 850 F. Supp. 633 (S.D. Ohio 1994) 13

National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) 20

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Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960) 20

Ratzlaf v. United States, ___ U.S. ___, 114 S. Ct. 655 (1994) 6, 18

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Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983) 6

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CONSTITUTIONAL PROVISIONS

U.S. Constitution, Art. VI, cl. 2. 3

STATUTES AND REGULATIONS

21 *U.S.C.* § 360a 7

21 *U.S.C.* § 360h 13

21 *U.S.C.* § 360h(d) 13, 18

21 *U.S.C.* § 360k 10

21 *U.S.C.* § 360k(a) 8, 17

21 *U.S.C.* § 360k(b) 12

28 *U.S.C.* § 2671 ..... 6 n.1

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TABLE OF AUTHORITIES—*(Continued)*

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Lora Lohr and Michael Lohr**

I. INTEREST OF AMICUS CURIAE

Amicus Curiae is the Plaintiffs' Legal Committee appointed by United States District Court Judge Louis C. Bechtle to coordinate litigation on plaintiffs' behalf in *In Re Orthopedic Bone Screw Products Liability Litigation*, MDL Docket No. 1014.

The cases involved in the *Orthopedic Bone Screw Products Liability Litigation* are actions in which plaintiffs suffered

injury as a result of the use of certain "fixation constructs" during spinal surgery and in which the manufacturers' liability is claimed to arise, in part, from conduct which is asserted to be in violation of numerous provisions of the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

Approximately 3,000 such cases have been transferred by the Judicial Panel for Multidistrict Litigation to Judge Bechtle of the United States District Court for the Eastern District of Pennsylvania for coordinated and/or consolidated pretrial proceedings pursuant to 28 *U.S.C.* §1407.

In the *Orthopedic Bone Screw Products Liability Litigation*, the defendants have taken the position that the Medical Device Amendments to the Food, Drug and Cosmetic Act preempt some or all of the plaintiffs' claims for relief because the products which caused plaintiffs' injuries are medical devices.

The Court's decision in the instant matter concerning the nature and extent of federal preemption of tort/product liability claims against the manufacturers of medical devices may have an impact on the ultimate disposition of the preemption issue in the *Orthopedic Bone Screw Products Liability Litigation*. Accordingly, the Amicus Curiae has an obvious interest in the resolution of that issue before this Court.

II. SUMMARY OF THE ARGUMENT

The Medical Device Amendments to the Food, Drug and Cosmetic Act limit preemption to state law requirements "with respect to a device intended for human use." Accordingly, the statute preempts only state law requirements that are specifically targeted at medical devices as distinguished from legal requirements of general applicability such as state tort law and products liability principles. This interpretation is one which is required: (1) by the plain meaning of the statute; (2) by the presumptions against preemption; (3) by the principle that obliges courts to defer to regulatory interpretations of a statute; (4) by consideration of the text and structure of the Medical Device Amendments; (5) by the principle of statutory

construction which requires that all the language of a legislative enactment be given effect; and (6) by the principle of statutory construction which examines legislative history to ascertain whether and to what extent Congress intended to preempt state law.

Moreover, by limiting preemption to establishment or enforcement of state "requirements" which are "different from or in addition to" federal requirements established pursuant to the Medical Device Amendments, it is clear that Congress did not intend to preempt state law damage claims which arise from conduct in violation of federal requirements imposed under the Medical Device Amendments. This construction is supported by the plain meaning of the statute, by the principle of statutory construction that requires that all the language of a legislative enactment be given effect and by the principle that requires deference to an agency's interpretation of a statute which it is entrusted to enforce.

III. ARGUMENT

A. General Principles of Federal Preemption Analysis

Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." *U.S. Constitution*, Art. VI, cl. 2. Thus, since the Court's decision in *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 403, 427 (1819), the Supreme Court has held that Congress can displace state law.

The question of federal preemption, however, implicates serious principles of federalism which require that "unintended encroachment on the authority of the States" be avoided. *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 113 S. Ct. 1732, 1737 (1993). Therefore, preemption analysis must begin "with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Accordingly, the Courts "will interpret a statute to pre-empt the traditional state powers only if that result is 'the

clear and manifest purpose of Congress.'" *Department of Revenue of Oregon v. ACF Industries, Inc.*, ____ U.S. ____, 114 S. Ct. 843, 851 (1994), quoting *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). *Accord, e.g., Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) ("The purpose of Congress is the ultimate touchstone" of preemption analysis); *Retail Clerks International Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963) ("The purpose of Congress is the ultimate touchstone.").

Congressional intent to preempt state law may be implied either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively or when state law is in actual conflict with federal law. *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990). Implied actual conflict preemption occurs where it is "impossible for a private party to comply with both state and federal requirements" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Freightliner Corp. v. Myrick*, ____ U.S. ____, 115 S. Ct. 1483, 1487 (1995), quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *English*, 496 U.S. at 79.

Congress may also provide expressly for preemption of state laws. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Where Congress expressly provides for preemption of state laws, it is usually inappropriate to find implied preemption. *Cipollone*, 505 U.S. at 517; *Freightliner*, 115 S. Ct. at 1488. As the Court held in *Cipollone:* "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517.

Where a "statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transportation*, 507 U.S. at ____, 113 S. Ct. at 1737. However, where the meaning of an express preemption provision is

unclear or in doubt, there are six bedrock principles of statutory construction that the Courts must apply in ascertaining Congressional intent to displace state law.

First, under the "*Chevron* doctrine" enunciated by this Court, when an agency is entrusted with the responsibility to administer legislation, its interpretation of the meaning of that legislation is entitled to substantial deference by the Courts. *E.g., Babbitt v. Sweet Home Chapter of Communities for a Great Oregon*, ____ U.S. ____, 115 S. Ct. 2407, 2416 & 2418 (1995); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984); *Bowels v. Seminole Rock & Sand Co.*, 325 U.S. 410, 413-14 (1945). This doctrine was recently and firmly emphasized by this Court in the *Sweet Home* case where the Court deferred to the interpretation of a statute by an agency which had been "delegated broad administrative and interpretive power." *Sweet Home*, 115 S. Ct. at 2418.

Second, as a matter of comity dictated by principles of federalism, there is a strong presumption against preemption if it would mean superseding a state's historic police powers, which include the regulation of health and safety matters. *See, e.g., Hillsborough County, Fla. v. Automated Medical Labs, Inc.*, 471 U.S. 707, 718 (1985); *Rice*, 331 U.S. at 230. Given this "strong presumption," preemption enactments are to be read "fairly but . . . narrowly" in relation to state laws governing health and safety. *E.g., Cipollone*, 505 U.S. at 523.

Third, there is an even more compelling presumption that Congress would not, in the exercise of its plenary powers, "remove all means of judicial recourse for persons injured" by preempting traditional damage remedies available to injured parties under state law without affording a substitute damage remedy under federal law.[1] *E.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 250-51 (1984); *United Construction Workers v.*

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[1] Although this presumption against preemption is rooted in notions of federalism and the basic notions of fairness inherent in the statutory construction process, the presumption serves federal interests in a very practical way. Where a federal agency does not comply with its own regulations and

Laburnum Construction Corp., 347 U.S. 656, 663-64 (1954). As the Court opined in *Silkwood*, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood*, 464 U.S. at 251.

Fourth, evidence of a preemptive purpose may be derived from "the text and structure" of the legislation at issue. *See CSX Transportation, Inc.*, 507 U.S. at _____, 113 S. Ct. at 1737; *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983). *See also Sweet Home*, 115 S. Ct. at 2418 (interpretation based on "text and structure").

Fifth, in construing preemption statutes, the courts are obliged to follow the general principle of statutory construction which presumes that there is no surplusage in the language employed by Congress and therefore requires that all of the language of the legislative enactment be given effect. *See Sweet Home*, 115 S. Ct. at 2413; *Ratzlaf v. United States*, _____ U.S. _____, 114 S. Ct. 655, 659 (1994); *Macky v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 837 (1988).

Finally, legislative history plays an important role in ascertaining whether and to what extent Congress intended to preempt state law. *ACF Industries*, 114 S. Ct. at 851-52; *Silkwood*, 464 U.S. at 256. The Court's decision in *Silkwood* provides a good example of the application of this principle. There, the plaintiff sought to recover damages for injuries caused by a plutonium release at a nuclear facility regulated by the Nuclear Regulatory Commission. Even though the Court recognized

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injury results, the injured party may bring a federal tort claim against the United States under the Federal Tort Claims Act, 28 U.S.C. §2671 *et seq. See Berkovitz v. United States*, 486 U.S. 531 (1988). To the extent that a right to relief against a private party is available under state or federal law for such injuries, the incentives to initiate action against the United States are diminished proportionately. Thus, a rule that presumes that Congress would not preempt traditional damage remedies available to injured parties under state law without affording a substitute damage remedy under federal law is one which serves to reduce the potential for litigation against the United States under the Federal Tort Claims Act.

that the federal government occupied the entire field of nuclear safety regulation, it held that there was no Congressional intent to preclude damage awards under state law to persons injured in nuclear accidents because of the legislative history underlying nuclear regulation. As the Court said:

> No doubt there is tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a State may nevertheless award damages based on its own law of liability. But as we understand what was done over the years in the legislation concerning nuclear energy, Congress intended to stand by both concepts and to tolerate whatever tension there was between them. We can do no less.

Silkwood, 464 U.S. at 256.

It is with these important and guiding principles in mind that we now turn to examination of the specific issue presented here—whether plaintiffs' damage claims arising from the use of dangerous medical devices are preempted by federal law.

B. Application of General Preemption Principles Requires the Conclusion That State Laws of General Applicability, Including the Common Law and Most Products Liability Laws, Are Not Preempted by Federal Law Governing Medical Devices

In 1976 Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act. *See* 21 *U.S.C.* §360a, *et seq.* The MDA contains an express preemption provision. It states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any

> requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 *U.S.C.* §360k(a).

The statute is unambiguous. By tying preemption to the presence of both a state requirement **"with respect to a device"** and an MDA requirement **"applicable to the"** device, it appears clear that preemption may not arise simply as the result of the existence of general legal requirements to which a device may be subject, but only as the result of laws and regulations that are specifically targeted at medical devices. This is consistent with prior Congressional enactments which have often drawn a distinction between preemption of specially targeted laws and preemption of generally applicable, background legal norms not directed at specific conduct in particular. *See, e.g., Cipollone*, 505 U.S. at 528-29 (no preemption because liability is predicated "on a more general obligation—the duty not to deceive"); *New York Telephone Co. v. New York State Department of Labor*, 440 U.S. 519, 550 (1979) (Congressional preemption of state power to "enforce . . . general laws is more difficult to infer than an intent to pre-empt laws directed specifically at concerted activity"); *United States Steelworkers of America v. Rawson*, 495 U.S. 362, 371 (1990) (the Court distinguished for purposes of labor law preemption between duties imposed on labor union by a collective bargaining agreement and generally applicable obligations such as "the duty of reasonable care owed to every person in society"); *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 107 (1992) (the Court held that the Federal Occupational Safety and Health Act of 1970 preempts only state law that "constitutes, in a direct, clear and substantial way, regulation of worker health and safety" and does not preempt "state laws of general applicability (such as laws regarding traffic safety or fire safety)"

despite their demonstrable effect on occupational safety).

However, in view of the conflicts that have developed in the Courts of Appeal in interpreting Section 360k it is certainly plausible to suggest that the reach of the statute is ambiguous. Given this, one must apply the six bedrock principles of preemption analysis outlined above to determine the extent to which Section 360k was intended to eliminate the availability of damage remedies under state law for injuries caused by medical devices.

Unquestionably, state tort law relates to matters of health and safety. *See* W. Prosser, *Handbook of the Law of Torts*, §5 at 23 (4th ed. 1971); Prentis and Roszkowski, *"Tort Reform" and the Liability "Revolution": Defending Strict Liability in Tort for Defective Products*, 27 *Gonz.L.Rev.* 251 (1992). In addition, there is no private right of action to recover damages or other relief under the MDA. *See, e.g., Bailey v. Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995); *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33 (M.D. Pa.), *aff'd without opinion*, 902 F.2d 1558 (3d Cir. 1989). Given the strong presumption against preemption of state laws relating to health and safety and the extreme admonition against adopting rules of preemption that would leave injured victims without a remedy, the preemption provision of the MDA should be given the narrowest reasonable construction in relation to state tort laws.

Plainly, a fair but narrow reading of Section 360k is that state law will not be preempted unless there is both a state requirement that specifically applies "with respect to a device" (as distinguished from a law of general application) and a federal requirement relating to "the" device and having the same subject matter as the state requirement, and then only to the extent that the state law imposes requirements which are "different from or in addition to" the specific federal requirement.

This is precisely the construction adopted by the FDA in regulations which it promulgated in 1978. These regulations,

intended to implement the provisions of Section 521, 21 *U.S.C.* §360k, specifically provide:

> State or local requirements are preempted only when the Food and Drug Administration has established **specific counterpart regulations** or there are other **specific requirements** applicable to a **particular** device under the act, thereby making any existing divergent State or local requirements **applicable to the device** different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> **(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.**
>
> **(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.**

21 *C.F.R.* §808.1(d)(1) & (2) (emphasis supplied).

Because most state tort law and products liability rules are laws of "general applicability" not specifically directed towards the regulation of medical devices, application of the syllogism contained in this regulation will not ordinarily permit

preemption of state laws governing liability for damages caused by injurious medical devices.

Since 1984, the FDA has consistently taken this position. For example:

> [I]n an Advisory Opinion issued under 21 *C.F.R.* §808.1, the Office of the Chief Counsel for the FDA stated:
>
> > Under section 521(a) [21 U.S.C. §360k] of the act, the act preempts only State and local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1435 (C.D. Cal. 1994) (emphasis in original).

In 1988 the FDA reiterated this position in a letter from Joseph M. Sheehan, Chief of its Regulations Staff, which stated:

> As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that

section 521 does not preempt general product liability requirements.[2]

And most recently, the FDA filed an Amicus Brief in *Talbot v. C.R. Bard, Inc.*, reasserting its position that plaintiffs may pursue damage remedies for injuries caused by federally regulated medical devices. *See Talbot v. C.R. Bard, Inc.*, 63 F.3d 25, 30 (1st Cir. 1995), *cert. pet. filed* (Feb. 16, 1996). *See also Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 247 n.8 (E.D. Pa. 1990) ("It is not the intent of FDA to influence the civil tort liability of the manufacturer").

Because the FDA is the agency charged with responsibility for administering the MDA, its views are entitled to substantial deference by the courts. *See* p. 5, *supra*. Indeed, judicial deference to the FDA's interpretation of the preemption provisions of the MDA should be particularly strong in light of the fact that Congress expressly made the FDA the arbiter of preemption by specifically authorizing it to allow exemptions from federal preemption in Section 521(b) of the statute, 21 *U.S.C.* §360k(b). *See Sweet Home*, 115 S. Ct. at 2418 (requiring substantial deference to regulatory interpretation of statutory language where agency given "broad administrative and interpretive power").

A narrow construction which holds that Section 360k should not preempt state laws of general applicability, including state tort law, is supported by the principle of statutory construction that eschews statutory surplusage and requires that every portion of a statute be accorded effect. Section 360k does *not* provide that "no state may establish or continue in effect any requirement which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." If it had done so, it would be clear that all state law "requirements" were encompassed within the ken of the statute. Rather, Congress

[2] A copy of this letter is included in the Appendix to the Cross-Petitioners' Brief at p. 14a.

chose statutory language that prohibits states from establishing such requirements only "with respect to a device intended for human use." In order to avoid a statutory construction that renders this language surplusage and in order to give independent semantic significance to these words, it is necessary to construe the language as limiting preemption of state law requirements to those which are specifically targeted at medical devices intended for human use rather than those applying broadly to all state law requirements, as would be the case if the limiting statutory language were not present.

The FDA's narrow interpretation of Section 360k(a) is also supported by reference to the "text and structure" of the MDA as a whole. Specifically, 21 *U.S.C.* §360h allows the FDA to provide for "repair, replacement or refund" in situations where the agency determines that a device "presents an unreasonable risk" or "was not properly designed or manufactured" due to the failure of a "manufacturer, importer, distributor, or retailer of the device." *See* 21 *U.S.C.* §360h. Subparagraph (d) of that section provides:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

Therefore, the statute specifically contemplates state law liability and damages notwithstanding the preemption provisions of Section 360k. *See Michael v. Shiley*, 46 F.3d 1316, 1326 (3d Cir.), *cert. denied*, _____ U.S. _____, 116 S. Ct. 67 (1995); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 & 1344 (11th Cir. 1995) ("savings clause [Section 360h] almost certainly prohibits a holding that the MDA preempts *all* state law liability"), *cert. granted*, _____ U.S. _____, 116 S. Ct. 806 (1996); *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 636 (S.D. Ohio 1994). This

buttresses the agency's narrow interpretation of Section 360k(a) which excludes product liability laws and remedies of general application from the scope of MDA preemption.

Finally, the legislative history convincingly supports the FDA's narrow interpretation of MDA preemption—that state laws of general applicability such as the common law and most product liability statutes, are not preempted by Section 360k(a). The Medical Device Amendments were passed in response to rapid technological changes in the medical device field and the perceived inadequacy of existing law to protect consumers from "increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." *S.Rep.No.* 33, 94th Cong., 2d Sess. 5, *reprinted in* 1976 *U.S. Code Cong. & Admin. News* 1070, 1075. The goal of the legislation was to "modify the underlying law in ways that will result in greater protection of the public health." *H.R. Rep.* No. 808, 101st Cong. 2d Sess. 13 (1990). As the sponsor of the bill stated, when introducing it on the Senate floor:

> The purpose of this legislation is to protect the health and safety of the American people . . . the legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for device malfunctions.

121 *Cong. Rec.* S. 6140 (April 17, 1975).

There is no question that products liability principles serve to promote public health and safety by establishing standards of conduct and providing a remedy for violation of those standards. *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 760 (S.D.N.Y. 1994); *Graham v. Wyeth Labs*, 666 F. Supp. 1483, 1493 (D. Kan. 1987); *MacGillivray v. Lederle Laboratories*, 667 F. Supp. 743, 745 (D.N.M. 1987); W. Prosser, *Handbook of the Law of Torts* §5 at 23 (4th ed. 1971). Therefore, eliminating tort liability for dangerous medical devices decreases the quantum of protection available to the public, denies the "benefit of the doubt" to the consumer and is thus incompatible with the

fundamental purpose of the legislation to provide greater protection of the public health. Thus, an interpretation of Section 360k which preserves, to the extent possible, the availability of traditional common law remedies is consistent with the central animating objective of the legislation.

Second, the MDA was enacted against the background of substantial litigation concerning injuries caused by medical devices, particularly the Dalkon Shield IUD.[3] In this context, a proposal to immunize medical device manufacturers from liability would, no doubt, have generated considerable controversy. Experience with similar measures suggests that if preemption were intended by Congress there would have been an extensive discussion of alternatives short of total immunity such as capping liability or perhaps eliminating strict liability and requiring a showing of negligence. Yet, tort reform is never discussed in the legislation or in its legislative history.

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[3]For example, the House Report on the 1976 Medical Device Amendments states:

> An example of a legitimate medical device which was marketed without adequate premarket testing is the Dalkon Shield. . . . By mid-1975, the Shield had been linked to sixteen deaths and twenty-five miscarriages. Presently, more than 500 lawsuits seeking compensatory and punitive damages totalling more that $400 million are pending against the manufacturer of the Shield. . . .

H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976). The Dalkon Shield was cited numerous times during the debates on the MDA in both the House and Senate. 122 Cong. Rec. H1719-1731 (daily ed. March 9, 1976); 121 *Cong. Rec.* S6139-6162 (daily ed. April 17, 1975). Liability claims eventually led the manufacturer of the Shield, A.H. Robins, to declare bankruptcy, at which time more than 300,000 women filed claims against the company for Dalkon Shield-related injuries and illness. *See* Richard B. Sobol, *Bending the Law: The Story of the Dalkon Shield Bankruptcy* (1991); Stephanie Goldberg, *Manufacturers Take Cover*, 72 A.B.A.J. 52 (July 1986). From 1974 to 1986, half of all product liability lawsuits filed in federal courts in the United States against pharmaceutical manufacturers were filed against A.H. Robins with respect to injuries or death allegedly caused by the Dalkon Shield. *See* Terence Dungworth, *Product Liability and the Business Sector: Litigation Trends in Federal Courts*, 52 (1988) (study for the RAND Corporation).

The only section of legislative history discussing the logic behind the adoption of Section 360k's language is House Report No. 853. *See H.R. Rep.* No. 853, 94th Cong., 2nd Sess. This report focuses on the need for nationwide uniformity in medical device approval in light of the haphazard regulatory efforts which states were beginning to adopt in the absence of meaningful federal regulation of medical devices. The House Report indicates that the Congressional purpose behind Section 360k was merely to prevent the states from establishing administrative mechanisms for clearance of medical devices in the absence of federal approval. *See H.R. Rep.* No. 853, 94th Cong., 2d Sess. at 45-46 (1976). Nowhere in the report or in any of the legislative history does Congress mention the effect of the legislation on state tort actions much less manifest an intent to limit or preclude such actions. *See Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459-60 (9th Cir. 1995); *Bravman*, 842 F. Supp. at 755 n.4, citing 121 *Cong. Rec.* 10, 687-710 (1975); *S.Rep.* No. 33, 94th Cong., 2d Sess. 3, *reprinted in* 1976 *U.S. Code Cong. & Admin. News* 1070-103; *House Conf. Rep.* No. 1090, 94th Cong., 2d Sess. 3, *reprinted in* 1976 *U.S. Code Cong., & Admin. News* 1103-18; *House Rep.* No. 853, 94th Cong., 2d Sess. (1976). *See also Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1300 (D. Minn. 1988). As a matter of logic, it is difficult to conclude that Congress intended to eliminate or seriously restrict tort liability resulting from dangerous medical devices without such a dramatic consequence even being mentioned in the legislative history, particularly in a piece of legislation which was specifically enacted against a background of extensive tort litigation concerning medical devices and which was specifically designed to add to the protections available to consumers of medical devices. *See, e.g., Kennedy*, 67 F.3d at 1459-60; *Callan*, 709 F. Supp. at 667; *Kociemba*, 680 F. Supp. at 1300; *Haudrich v. Howmedica, Inc.*, 267 Ill.App.3d 630, 204 Ill. Dec. 744, 642 N.E.2d 206, 214 (1994), *aff'd*, 1996 W.L. 19012 (Ill., Jan. 18, 1996).

Accordingly, application of the rules of preemption analysis frequently articulated by this Court amply warrants the conclusion that the MDA cannot and should not be construed as preempting legal requirements of general applicability such as the common law, tort law, and product liability principles. This is not to say that there will never be preemption of state tort law as applied to medical devices. A device-specific federal labeling regulation may, for example, preempt a state law failure-to-warn claim under the principle of implied actual conflict preemption discussed above. *See* p. 4, *supra; Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 (5th Cir. 1989). However, it is to say that in enacting Section 360k, Congress did not manifest an intent to preempt the operation of general state law requirements as applied to medical devices. Tort damage remedies should not be eviscerated simply because the offending agent is a medical device as opposed to some other type of harmful product.

C. Claims Arising From Conduct That Violates the Federal Medical Device Law Are Not Preempted

Preemption of state law under Section 360k is sharply limited by the language that expressly confines preemption to the establishment or enforcement of state law "requirements" which are "different from or in addition to" federal requirements established pursuant to the MDA. *See* 21 *U.S.C.* §360k(a). The only sensible construction of this language is that the MDA does not preempt state law damage claims which arise from conduct in violation of federal requirements imposed under the MDA itself.

Such a construction is supported by the plain meaning of the statute—to the extent that state law allows recovery for conduct which violates federal law, it does not impose "different" or "additional" requirements, but rather serves as a means to underscore and enforce the federal requirements. *See Michael v. Shiley*, 46 F.3d at 1328; *Sylvester v. Mentor Corp.*, 663 So. 2d 176, 180-181 (La.App. 3d Cir. 1995), *writ denied*, 95-2936, _____ So. 2d _____ (La., Feb. 16, 1996).

This interpretation is also supported by the principle of statutory construction which requires that all the language of a legislative enactment be given effect. *See, e.g., Sweet Home*, 115 S. Ct. at 2413; *Ratzlaf*, 114 S. Ct. at 659; *Macky*, 486 U.S. at 837. If preemption were triggered merely by the existence of a federal requirement having the same subject matter as a state requirement, then the language limiting preemption to state requirements which are "different from or in addition to" federal requirements would be meaningless surplusage, unless the imposition of a damage remedy under state law could be considered a "requirement" under the statute which is "different from or in addition to" the remedies provided by federal law. However, this Court has consistently held that the availability of a damage remedy under state law, as distinguished from the substantive obligation for which the law may afford that relief, is not a "requirement for purposes of preemption." *Cipollone*, 505 U.S. at 526; *American Airlines, Inc. v. Wolens*, _____ U.S. _____, 115 S. Ct. 817, 824 (1995). Therefore, in order to give effect to the limitation of preemption contained in the "different from or in addition to" language of the statute and the teachings of this Court that the provision of a damage remedy, by itself, does not impose a "requirement," it is essential to construe the statute as permitting the imposition of duties under state law to the extent that they are not different from or in addition to those imposed by federal law.

Moreover, an interpretation of the statute which allows damage remedies under state law for conduct in violation of a federal requirement carries into effect the express preservation of state law damage remedies provided for by Congress in Section 360h of the statute. *See* 21 *U.S.C.* §360h(d). Indeed, a contrary construction—that state law remedies are "requirements" that are preempted by the availability of FDA enforcement actions—would be directly contrary to the provisions of Section 360h(d), which expressly preserve "liability under federal or state law" for "damages." *See* 21 *U.S.C.* §360h(d); *see*

also Michael v. Shiley, 46 F.3d at 1326 (Congress "g[a]ve indications in 21 *U.S.C.* §360h that at least some common law remedies would remain in conjunction with FDA regulation"). And, to the extent that there is ambiguity on this point, the presumption against preemption of state law remedies requires resolution of that ambiguity in favor of a rule which preserves the existence of state law damage remedies. *See Cipollone*, 505 U.S. at 523; *Hillsborough*, 471 U.S. at 718; *Silkwood*, 464 U.S. at 250-51; *United Construction Workers*, 347 U.S. at 663-64.

An interpretation of the statute which preserves the availability of state law damage remedies to the extent that a manufacturer's conduct is in violation of federal law is also supported by the legislative history of the MDA. As we demonstrated earlier, Congress' sole purpose in enacting the preemption provisions of the MDA was to eliminate haphazard regulation of medical devices by the states and not to foreclose private parties from obtaining a remedy for injuries caused by unsafe medical devices. *See* Part III(B), *supra*. An interpretation of the MDA which permits plaintiffs to recover under state law for conduct that violates the MDA serves this legislative purpose.

Moreover, the FDA's own regulations, which the Court is obliged to apply under the *Chevron* doctrine, explicitly support the conclusion that the MDA does not preempt state law to the extent that it allows recovery for conduct that violates the federal law. Specifically, those regulations state:

> Section [360k(a)] does not preempt State or local requirements that are equal to, or substantially identical to, the requirements imposed by or under [federal medical device law].

21 *C.F.R.* §808.1(d)(2). *See Sweet Home*, 115 S. Ct. at 2416 & 2418; *Chevron*, 467 U.S. at 844; *Bowels*, 325 U.S. at 413-414.

Finally, a rule that permits state law claims to the extent that they are predicated on violations of federal medical device law does not transgress the established principle that there is no implied private right of action under the Food, Drug and Cosmetic Act for two discrete reasons.

First, when liability is imposed for conduct that violates the provisions of the Food, Drug and Cosmetic Act, it is imposed under principles of state law which employ statutes and regulations as applicable standards of care and allow damages when the state law prerequisites to damages such as proximate cause and injury are also established. *See, e.g., Stanton-By-Brooks v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 563-65 (3d Cir. 1983); *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455, 460-61 (4th Cir. 1960); *Toole v. Richardson-Merrell, Inc.*, 251 Cal.App. 2d 689, 703-04, 60 Cal.Rptr. 398 (lst Dist. 1967). Federal law has long recognized the appropriateness of this common law practice. *Id. Cf. Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986) (holding that a state law claim based on violation of the Food, Drug and Cosmetic Act was not a claim "arising under" federal law within the meaning of 28 *U.S.C.* §1331, but nowhere suggesting that a cause of action under state law did not exist).

Second, federal courts are less likely to recognize private rights of action under federal statutes where state law remedies are available. *See Cort v. Ash*, 422 U.S. 66, 78 (1975) (noting that the availability of an implied right of action under a federal statute turns, in part, on whether "the cause of action [is] one traditionally relegated to state law, in an area basically the concern of the States, so that it would be inappropriate to infer a cause of action based solely on federal law"). Thus, the failure of federal law to recognize an implied right of action under the Food, Drug and Cosmetic Act **strengthens** the argument that plaintiffs may seek relief under state law at least to the extent that state law does not impose requirements that are "different from or in addition to" the federal requirements.

In light of these considerations, the better-reasoned decisions in the Courts of Appeal have held that state law claims arising from conduct that violates the Federal Medical Device Law are not preempted. *E.g., National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 993 (8th Cir. 1994) ("when a statute only preempts state requirements that are different

from or in addition to those imposed by federal law [like the MDA], plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements"); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1281-82 (7th Cir. 1995), *cert. pet. filed* (Feb. 20, 1996) ("In the absence of a more explicit legislative or regulatory direction, we hesitate to say, therefore, that an adulteration claim based on a product's failure to meet PMA standards—standards that have been explicitly set forth by the FDA—does not survive MDA preemption. Such a claim seeks merely to enforce the federal standard, not to add requirements 'different from, or in addition to,' it"); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992) (preemption under the MDA is "limited to efforts by states to impose sanctions for compliance with federal regulations"); *Sylvester*, 663 So. 2d at 180-181 (we find no preemption of state law award of damages for violation of FDA's own requirements for a particular device); *Reiter v. Zimmer*, 897 F. Supp. 154, 160-162 (S.D.N.Y. 1995) ("a state action does not impose an 'additional requirement' simply because it might give rise to an obligation to pay money damages that might not arise under federal law . . . [plaintiffs'] negligent manufacturing claim, limited in scope to questions of compliance with existing FDA regulations and questions of proximate causation and damages, is an appropriate mechanism in support of federal law, and is therefore not preempted"); *Reiter v. Zimmer*, 830 F. Supp. 199, 204 (S.D.N.Y. 1993) ("refusing to extend preemptive reach of MDA to a negligence claim against a manufacturer that allegedly violated FDA requirements"); *Ministry of Health v. Shiley*, 858 F. Supp. at 1439 ("the MDA would *not* preempt claims that the manufacturer *negligently failed to comply with the FDA's regulations*, since a finding of wrongdoing would merely impose those regulations already imposed by the statute, and would not be 'different from or in addition to' those imposed by the MDA"); *Evraets v. Intermedics Intraocular, Inc.*, 29 Cal.App. 4th 779, 791, 34 Cal.Rptr. 2d 852, 859 (1994) ("State actions which echo or attempt to enforce

federal standards are not preempted"); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, _____ U.S. _____,115 S. Ct. 2614 (1995) ("Martello did not claim the AOSEPT he used did not comply with federal regulations").

Those appellate decisions which have extended preemption to claims arising from conduct in violation of the provisions of the MDA, like the Eleventh Circuit in the present matter, have done so primarily because of philosophical reasons or concerns with the difficulties in implementing such a rule. *See Lohr*, 56 F.3d at 1343 and *Talbot*, 63 F.3d at 29. Such philosophical or practical considerations are, however, immaterial. Under this Court's preemption jurisprudence, these considerations attendant to the question of preemption are a matter of legislative and not judicial concern. Therefore, in interpreting an express preemption provision, the sole question properly before a court is the extent to which the language used by Congress delimits the scope of preemption. By expressly providing that preemption of state requirements with respect to medical devices is limited to the establishment or enforcement of state law "requirements" which are "different from or in addition to" federal requirements established under the MDA, Congress plainly crafted such a limitation on preemption.

IV. CONCLUSION

For the foregoing reasons, Amicus Curiae respectfully submits that to the extent that the Opinion and Order of the United States Court of Appeals for the Eleventh Circuit found in favor of Cross-Petitioners, Lora Lohr and Michael Lohr, it should be affirmed and that to the extent that it ruled against them, the Opinion and Order should be reversed.

Respectfully submitted,

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Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

October Term, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF OF THE STATES OF FLORIDA, ARKANSAS, COLORADO, CONNECTICUT, INDIANA, KENTUCKY, MAINE, MARYLAND, MISSISSIPPI, MISSOURI, MONTANA, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OREGON, SOUTH DAKOTA, TENNESSEE, TEXAS, AND WEST VIRGINIA AS AMICI CURIAE IN SUPPORT OF LORA LOHR AND MICHAEL LOHR

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

THE INTEREST OF THE *AMICI CURIAE* 1

INTRODUCTION AND SUMMARY OF ARGUMENT 1

ARGUMENT 6

I. THE MDA DOES NOT PRE-EMPT ANY STATE-LAW CLAIMS FOR DAMAGES 6

A. Pre-emption Would Be Antithetical to the Congressional Purpose in Adopting the MDA . . . 7

B. Section 360k(a) Does Not Support Pre-Emption of State-Law Damages Claims 14

II. AT A MINIMUM, THE SECTION 510K PROCESS DOES NOT PRE-EMPT CLAIMS INVOLVING MEDICAL DEVICES THAT HAVE NOT RECEIVED FDA PRE-MARKET APPROVAL 18

CONCLUSION 20

TABLE OF AUTHORITIES

Case(s) — *Page(s)*

AMP, Inc. v. Gardner, 389 F.2d 825 (2d Cir.), *cert denied*, 393 U.S. 825 (1968) 7

Abbot v. American Cynamid Co., 844 F.2d 1108 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988) 9

Bethelem Steel Co. v. New York State Labor Relations Board, 330 U.S. 767 (1947) 2

CSX Transport, Inc. v. Easterwood, 113 S. Ct. 1732 (1993) 2

Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989) 11, 17

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 2, 6, 16

Department of Revenue of Or. v. ACF Industrial, Inc., 114 S. Ct. 843 (1994) 2

Florida Lime and Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963) 2, 18

Freightliner Corp. v. Myrick, 115 S. Ct. 1483 (1995) . 5, 18

Gade v. National Solid Wastes Management Association, 505 U.S. 88 (1992) 17

Garcia v. San Antonio Metropolitan Transit Authority, 469 U.S. 528 (1985) 3

Gregory v. Ashcroft, 501 U.S. 452 (1991) 3

Hawaiian Airlines, Inc. v. Norris, 114 S. Ct. 2239 (1994) 1

Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707 (1985) 18

Jones v. Rath Packing Co., 430 U.S. 519 (1977) 3

Kassel v. Consolidated Freightways Corp., 450 U.S. 662 (1981) 2

Kievlan v. Dahlberg Electronics, 144 Cal. Rptr. 585, 78 Cal. App. 3d 951 (Cal. App. 1978) 12

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert denied*, 114 S. Ct. 84 (1993) 13

Larsen v. Pacesetters Systems, Inc., 373 U.S. 132 (1963) 12

Maryland v. Louisiana, 451 U.S. 725 (1981) 1

New Jersey Guild of Hearing Aid Dispensers v. Long, 75 N.J. 544 (1978) 12

New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Insurance Co., 115 S. Ct. 1671 (1995) 1, 16

New York Telephone Co., v. New York State Department of Labor, 440 U.S. 519 (1979) 16

New York v. United States, 505 U.S. 144 (1992) 2

O'Gilvie v. International Playtex, Inc. 821 F.2d 1438 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988) . 11

Red Lion Broadcasting Co. v. FCC, 395 U.S. 367 (1969) 12

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) . . . 2

Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992) 13

Smith v. Pingree, 651 F.2d 1021 (5th Cir. 1981) 11

Stamps v. Collagen Corp., 984 F.2d 1412 (1st Cir.), *cert. denied*, 114 S. Ct. 6 (1993) 13

Tetuan v. A.H. Robins Co., 738 P.2d 1210 (Kan. 1987) . . 11

U.S. Term Limits, Inc. v. Thornton, 115 S. Ct. 1842 (1995) 3

United States v. An Article of Drug...Bacto-Unidisk, 394 U.S. 784 (1969) 7

United States v. Lopez, 115 S. Ct. 1624 (1995) 2

United Steelworkers of America v. Rawson, 495 U.S. 362 (1990) 16

Statutes

21 U.S.C. § 360h(d) 5, 17

21 U.S.C. § 360k(b) 5, 17

21 U.S.C. § 360k(a) 9, 14

Regulations

21 C.F.R. § 10.85(e) 9

21 C.F.R. § 807.97 . . . . . 5, 19

21 C.F.R. § 808.1(b) 10

21 C.F.R. § 808.20(c)(1) 10

Other authorities

42 Fed. Reg. 30385 (1977) 11

43 Fed. Reg. 18,663 (1978) 8, 11

Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 922–23 n.126 (1994) 8, 9

INTEREST OF THE *AMICI CURIAE*

Pursuant to Supreme Court Rule 37.5, the signatory States respectfully submit this brief as *amici curiae* in support of respondents/cross-petitioners Lora and Michael Lohr.

Amici have a strong interest in this case because they are responsible for the enforcement of laws safeguarding public health, safety, and welfare. In addition, *amici* have a strong interest in preserving the appropriate balance of authority between the States and the federal government. Through the evolution of their common law and by legislative enactments, the States have developed and refined their tort systems to balance the needs and rights of victims against the interest of manufacturers of potentially dangerous or defective products.

Pre-emption analysis asks whether congressional intent to displace state law is so clear and manifest as to give adequate notice to the States of the impending removal of their authority. This question is particularly important in cases like this one, where the asserted pre-emptive effect of the federal statute is so dramatic. *Amici* urge this Court to hold that the Medical Device Amendments of 1976 (MDA) do not displace state-law damages claims, because that act did not give the States the requisite clear notice of its sweeping pre-emptive effect.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case is rooted in principles of federalism. Our federalist system requires that "consideration" of pre-emption under the Supremacy Clause "start" with the basic "presumption that Congress does *not* intend to supplant state law." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co* , 115 S. Ct. 1671, 1676 (1995) (emphasis added); *see also Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Pre-emption of state efforts to protect health and safety "should not be lightly inferred." *Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994) (internal quotation omitted). Local laws relating to health and safety are "those 'the Court

has been most reluctant to invalidate.'" *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 670 (1981) (citation omitted).

Hence, state law is pre-empted only if there is "an unambiguous congressional mandate to that effect." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 147 (1963). "[P]re-emption will not lie unless it is the 'clear and manifest purpose of Congress.'" *CSX Transp., Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). "Any indulgence in construction should be in favor of the States, because Congress can speak with drastic clarity whenever it chooses to assure full federal authority, completely displacing the States." *Bethlehem Steel Co. v. New York State Labor Relations Bd.*, 330 U.S. 767, 780 (1947) (Frankfurter, J., dissenting).

The presumption against pre-emption is especially strong when Congress has failed to provide a separate federal remedy for a person injured by tortious conduct, because "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). The MDA does not provide a remedy for a person injured by a negligently designed or manufactured device.

The stringent showing required for pre-emption rests on fundamental "[p]rinciples of federalism." *Department of Revenue of Or. v. ACF Indus., Inc.*, 114 S. Ct. 843, 850 (1994). This Court has shown great solicitude for state sovereignty. It has ruled, for example, that the Commerce Clause is not all-encompassing, *see United States v. Lopez*, 115 S. Ct. 1624, 1631 n.3, 1632, 1634 (1995); that Congress may not "commandeer the legislative processes of the States by directly compelling them to enact and enforce a federal regulatory program," *New York v. United States*, 505 U.S. 144, 170 (1992) (citation omitted); and that, absent clear congressional intent, federal employment statutes such as the Age Discrimination in Employment Act of 1967 should not be construed as applying to state

judges and other state constitutional officers, given the importance of the "federalist structure of joint sovereigns" and the need for "a proper balance between the States and the Federal Government." *Gregory v. Ashcroft*, 501 U.S. 452, 459 (1991).

One of the vital "procedural safeguards inherent in the structure of the federal system," *see Garcia v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528, 552 (1985), is the requirement of a crystal-clear statement of congressional intent before the States are stripped of the right to govern themselves and to protect their citizens against unsafe products. "[I]nasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise. '[T]o give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'" *Gregory*, 501 U.S. at 464 (quoting L. Tribe, American Constitutional Law § 6-25, at 480 (2d ed. 1988)); *see also U.S. Term Limits, Inc. v. Thornton*, 115 S. Ct. 1842, 1887 n.12 (1995) (Thomas, J., joined by Rehnquist, C.J., and O'Connor and Scalia, JJ., dissenting) (quoting the same sentence of American Constitutional Law and describing *Gregory* as "applying this argument").

Moreover, the overall presumption against pre-emption "provides assurance that 'the federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (citation omitted). As Judge Kenneth Starr and Judge Patrick Higginbotham explained in their seminal monograph on the subject:

> When courts consider whether Congress intended to preempt state laws,...the nation's commitment to federalism would seem to argue for an *especially clear* statement of congressional intent to oust states from their

> traditional legislative functions. For if in close or uncertain cases a court proceeds to preempt state laws where that result was not clearly the product of Congress' considered judgment, the court has eroded the dual system of government that ensures our liberties, representation, diversity, and effective governance.

Judge Kenneth Starr & Judge Patrick E. Higginbotham, *et al.*, *The Law of Preemption: A Report of the Appellate Judges Conference* 47 (1991) (emphasis added).

I.

The Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 301–393, contain nothing approaching a clear statement of congressional intent to pre-empt state tort actions. The only reference to state law damages claims in the text of the MDA is a savings provision, not a pre-emption provision. This feature is not surprising in light of Congress' overall purpose in adopting the MDA: to expand consumer protection against dangerous medical devices, not to displace civil claims by victims of those devices. The MDA was an addition to the Federal Food, Drug, and Cosmetic Act of 1938, a statute that was designed to allow — and has always been construed to permit — consumers to bring state-law damages claims for injuries caused by unsafe drugs, foods, or cosmetics.

The MDA does contain a pre-emption provision, § 360k(a), but that section should be construed as addressing only state statutes, administrative regulations, and ordinances. Section 360k(a) uses the term "requirement" three times; only once, in the context of state-law requirements, is it even arguably ambiguous. In the other two references, § 360k(a) clearly uses "requirement" to mean positive enactments, not state-law claims for damages.

Moreover, § 360k(a) pre-empts only state-law requirements "with respect to a device." The text of the statute, the interpretation of the FDA, and the prior decisions of this

Court all indicate that this phrase does not include generally applicable norms of state law, such as common-law rules regarding fraud and negligence. This Court has always drawn a significant distinction between the pre-emption of specially targeted laws and pre-emption of generally applicable, background rules.

The MDA's text and structure also reinforce the conclusion that it does not pre-empt state-law damages claims. For example, the procedure by which States may petition the FDA for exemptions from pre-emption, 21 U.S.C. § 360k(b), and the reference to state-law claims for damages in the event of recalls of unsafe devices, 21 U.S.C. § 360h(d), both indicate that Congress did not intend to pre-empt state-law damage claims.

II.

Even if the MDA's pre-emptive effect extended to *some* state-law damages claims, it would not displace the claims at issue in the instant case. Like *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995), the instant case involves a product which was not approved and for which there was no governing federal safety regulation. Although *some* medical devices have entered the market pursuant to the FDA premarket approval ("PMA") process, which enables the agency to determine whether a proposed product provides "reasonable assurance of its safety and effectiveness," 21 U.S.C. § 360c(a)(C), the device at issue did *not*.

Rather, the defective pacemaker that allegedly injured Ms. Lohr entered the market as the substantial equivalent of another pacemaker that was on the market before the MDA was adopted. 21 U.S.C. § 360e(b)(1)(B). Regulatory inquiry focused not on *safety*, but on whether the defective pacemaker was *equivalent* to one already on the market. In such circumstances, the FDA has declared that its acceptance of a claim of "substantial equivalence" does "not in any way denote official approval of the device." 21 C.F.R. § 807.97.

Congress itself, in strengthening the MDA in 1990, warned that § 510(k) approval "is not equivalent to an approval by the FDA of the device's safety and effectiveness." H.R. Rep. No. 808, 101st Cong., 2d Sess. 1990, *reprinted in* 1990 U.S. Code Cong. & Admin. News 6307.

This Court should hold that, at a minimum, the § 510k process does not result in "requirements" that could pre-empt state law damages claims arising from devices that never received FDA premarket approval.

ARGUMENT

I. THE MDA DOES NOT PRE-EMPT ANY STATE-LAW CLAIMS FOR DAMAGES

"[T]here is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law damages actions." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). Instead, the pre-emptive effect of federal legislation must be assessed on a statute-by-statute basis, in light of the traditional presumption against pre-emption. Thus, in *Cipollone*, this Court held that the 1965 Federal Cigarette Labeling and Advertising Act "is best read as having superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels." 505 U.S. at 518. In contrast, considering the "broad sweep" of the language in the Public Health Cigarette Smoking Act of 1969 and the legislative history of

that act, this Court found certain state-law damages claims pre-empted.[1]

A close analysis of the MDA and its legislative history indicates that it, too, was never intended to displace state-law damages claims.

A. PRE-EMPTION WOULD BE ANTITHETICAL TO THE CONGRESSIONAL PURPOSE IN ADOPTING THE MDA

The MDA is a consumer protection statute, not one that granted device manufacturers sweeping immunity from state-law claims for damages. Prior to the MDA's enactment, the FDA was not authorized to review a medical device — regardless of the dangers it posed — for safety and efficacy before it was marketed unless the agency could persuade a court to treat the device as a drug.[2] The MDA was adopted to protect consumers by giving the agency premarket regulatory author-

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1 Three Justices would have held in *Cipollone* that the 1969 Act did not pre-empt any common-law damages claims, on the ground that "[t]he effect of tort law on a manufacturer's behavior is necessarily indirect." 505 U.S. at 536 (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part and dissenting in part). Justice Blackmun also noted: "The principles of federalism and respect for state sovereignty that underlie the Court's reluctance to find pre-emption where Congress has not spoken directly to the issue apply with equal force where Congress has spoken, though ambiguously. In such cases, the question is not *whether* Congress intended to pre-empt state regulation, but to what *extent*. We do not, absent unambiguous evidence, infer a scope of pre-emption beyond that which clearly is mandated by Congress' language." *Id.* (emphasis in the original).

2 *See, e.g., United States v. An Article of Drug...Bacto-Unidisk*, 394 U.S. 784 (1969) (cardboard disk impregnated with antibiotic); *AMP, Inc. v. Gardner*, 389 F.2d 825 (2d Cir.), *cert. denied*, 393 U.S. 825 (1968) (suture product).

ity over dangerous devices.[3] Introducing the bill on the Senate floor, its sponsor, Senator Kennedy, explained that "[t]he legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. S6140 (Apr. 17, 1975). The FDA has recognized that "[t]he entire thrust of the Amendments is to provide FDA with new and additional authority to assure that only safe and effective medical devices are permitted on the market." 43 Fed. Reg. 18,663 (1978).

The leading scholarly analysis on the pre-emptive effect of the MDA reports that, "except for a few passing references to the need to avoid slowing innovations in medical technology" — chiefly as a result of *federal* (not state) *overregulation*[4] — "the critical, and endlessly repeated focus of congressional attention was to protect consumers from dangerous devices." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 922–23 n.126 (1994). Indeed, since medical devices were virtually *unregulated* prior to 1976, it is paradoxical to suggest that Congress adopted the MDA to "deregulate" medical devices in order to promote innovation. If Congress had wished to achieve *that* objective, it simply would have done nothing at all.

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3 H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976) ("Absent clear, statutory authority to regulate medical devices, the FDA cannot safeguard the health of the American public by assuring the safety and effectiveness of [medical devices]."); S. Rep. No. 33, 94th Cong., 2d Sess. 5 (1976) ("Although many lives have been saved or improved by [medical devices], the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the complicated technology involved in their manufacture and use.... Increasing numbers of patients have been exposed to increasingly complex devices which pose serious risks if inadequately tested or improperly designed or used.").

4 *E.g.*, H.R. Rep. No. 853 at 10 ("excessive or ill-conceived *Federal* device regulation would stifle progress in this field") (emphasis added).

The MDA manifests no intent to insulate manufacturers from damages liability under state law. There is no express reference in the statute to state-law damages claims, but only to "requirement[s]," 21 U.S.C. § 360k(a), which are best understood as state statutes, administrative rules, ordinances, and other positive enactments. *See* Part I-B, *infra*. "A careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Adler & Mann, *supra*, at 923 n.128.

In constructing this regulatory framework, Congress clearly legislated against a background understanding that state tort remedies would remain available to injured consumers. The MDA is, after all, an *amendment* to the Food, Drug, and Cosmetic Act of 1938, a statute that has never been accorded broad pre-emptive effect.[5] Indeed, a proposed provision for a federal cause of action in the original Federal Food, Drug, and Cosmetic Act was deleted as being duplicative of existing state law.[6]

In the wake of the MDA's adoption, the FDA released an advisory opinion — which "represents the formal position of the FDA" and is binding on the agency, 21 C.F.R. § 10.85(e) — explaining to interested parties that the MDA did not bar

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5 *E.g.*, *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 & n.1 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988).

6 Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce, 73d Cong. 2d Sess. 400, 403 (1933).

common-law claims.[7] Similarly, in deciding whether to require medical device manufacturers to report injuries caused by their devices, the FDA assumed that product liability litigation would continue, even if device manufacturers complied with FDA requirements. *E.g.*, 45 Fed. Reg. 76183, 76188 (1980); 48 Fed. Reg. 24014, 24022 (1983); 49 Fed. Reg. 36326, 36331, 36337 (1984).[8]

After the MDA's passage courts generally allowed state-law tort claims to proceed against medical device manufacturers. For example, the Tenth Circuit affirmed a multimillion-dollar judgment in a toxic shock syndrome case, rejecting the manufacturer's claim "that its compliance with FDA standards entitled it to judgment as a matter of law." *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438, 1443 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988). Several federal courts, as well as the Supreme Court of Kansas, held that the MDA did not bar claims arising from defective intrauterine devices (IUDs).[9] The Fifth Circuit held that state regulations regarding the fitting, sale, and packaging of hearing aids were not pre-empted.[10] And the New Jersey Supreme Court determined that state requirements regarding hearing aids were invalid only if they conflicted with specific federal regulations

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7 *See* Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to Robert E. Manchester, National Women's Health Network (Mar. 8, 1984), reprinted at Pet. App. 4a–6a in *Lohr v. Medronic, Inc.*, No. 95-886; *see also* Letter from Joseph Sheehan, Chief, Regulation Staff, Food and Drug Administration, to Cindy Whaley, Esq. (Feb. 2, 1987), reprinted at Pet. App. 7a in *Lohr v. Medronic, Inc.*, No. 95-886.

The FDA also described § 360(k)(a) as "prescrib[ing] a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law *(whether established by statute, ordinance, regulation, or court decision)*, which is different from or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act." 21 C.F.R. § 808.1(b) (emphasis added). The italicized language simply means that the pre-emptive effect of the MDA extends to court decision construing state statutes, ordinances, and regulations. *See* 43 Fed. Reg. 18,663 (1978) ("When determining whether a State or local requirement is preempted, however, the Commissioner will consider how the requirement is interpreted and applied, not merely the literal language of the applicable statute."). This meaning is especially clear in the context of the FDA's regulations addressing exemptions from pre-emption. *See* 21 C.F.R. § 808.20(c)(1) (States seeking exemptions from pre-emption must submit "a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision"; "[i]f the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations").

8 Other FDA statements shows that the agency narrowly construed the preemptive effect of § 360k(a) and limited the concept of a "requirement" to state statutes, regulations, and ordinances. *See, e.g.*, 42 Fed. Reg. 30385 (1977) ("An exemption will be granted only for those device-related requirements that have the force and effect of law, i.e., have been enacted, promulgated or issued in final form. However, an application may be submitted after the establishment of the statute or regulation by the State or local government, but before the effective date of the requirement."); 43 Fed. Reg. 18663 (1978) (state statute prohibiting sale of adulterated or misbranded devices not pre-empted because it "applies to the person who would sell the device — and thereby cause the violation — and not to the device itself").

9 *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 664 (D. Md. 1989); *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1232–33 (Kan. 1987).

10 *Smith v. Pingree*, 651 F.2d 1021, 1024–25 (5th Cir. 1981).

on the topic.[11] When it amended the MDA in 1990, Congress expressed no disagreement with the narrow interpretation of the Act's pre-emptive effect that had been advanced by the FDA and many lower courts.[12] In fact, Congress explained that the purpose of the 1990 amendments was to "modify the underlying law in ways that will result in *greater* protection of the public health." H.R. Rep. No. 808, 101st Cong., 2d Sess. 13 (1990) (emphasis added).[13]

There is thus no basis for concluding that the States had any notice at all — much less "clear" notice — that the MDA would work a dramatic and unprecedented withdrawal of remedies available to injured consumers. Tellingly, not until eighteen years after the MDA's passage did courts begin to accord it broad pre-emptive effect.[14]

Nevertheless, medical device manufacturers insist that in 1976 Congress bestowed on them a blanket immunity from the state-law damages claims of the victims of defective and unsafe medical devices — even if the FDA never determined that the devices were safe. *See* Part II, *infra*. And the manufacturers' argument would apply equally to state *criminal*, as well as *civil*, liability — so that a company guilty of intentional or criminally negligent wrongdoing could not be punished under *any* form of state law.[15]

Medical devices include more than 1,700 different kinds of products, ranging from the everyday (*e.g.*, cotton swabs) to the highly complex (*e.g.*, heart pacemakers or hip replacements). It is simply inconceivable that in 1976 Congress meant to confer — or that the States would have tolerated — a blanket immunity for the manufacturers of all such products. Indeed, the MDA was prompted in large part by the emerging scandal of the "Dalkon Shield" (the A.H. Robins Company's brand name for an intrauterine birth control device or IUD), which Congress singled out as "[a]n example of a legitimate medical device which was marketed without adequate premarket testing." H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976). The Dalkon Shield was cited numerous times during the debates on the MDA in both the House and Senate.[16] A supreme irony of this case is that, if the Dalkon

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11 *New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 572 (1978); *see also Kievlan v. Dahlberg Electronics*, 144 Cal. Rptr. 585, 78 Cal. App. 3d 951 (Cal. App. 1978) (no pre-emption of California prohibition against hearing aid manufacturer representing that products have any effect on diseases or disorders of the ear).

12 This Court accords "great weight" to an amending Congress' interpretation of the underlying statute. *E.g., Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380–381 & n.8 (1969).

13 The Hawaii Supreme Court explained:

> [The legislative history of the Medical Device Amendments] reveals that Congress was concerned with *increasing* the protection afforded medical device consumers under existing law rather than with *restricting* or reforming the law in existence at the time of the Act. Moreover, in 1990, subsequent to FDA promulgation of § 808.1(d), Congress amended the Medical Device Amendments of 1976....The 1990 amendments left § 360k untouched, providing evidence that § 808.1(d) is an accurate reflection of Congressional intent under § 360k. *Larsen v. Pacesetters Systems, Inc.*, 837 P.2d 1273, 1281 (Haw. 1992) (emphasis added).

14 *See, e.g., Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

15 *Cf. United States v. C.R. Bard, Inc.*, 848 F. Supp. 287 (D. Mass. 1994) (device manufacturer pleading guilty to 391 criminal counts of violations of federal law).

16 *E.g.*, 122 Cong. Rec. H1719–1731 (daily ed. Mar. 9, 1976); 121 Cong. Rec. S6139–6162 (daily ed. Apr. 17, 1975).

Shield tragedy occurred today, Medtronic's argument would mean that the MDA would bar resultant tort claims.

In sum, as two commentators have observed, "it is inconceivable that as Draconian a measure as preempting common law tort claims founds its way into the MDA in 1976 without one word from concerned members of Congress." Adler & Mann, *supra*, at 940.

B. SECTION 360K(A) DOES NOT SUPPORT PREEMPTION OF STATE-LAW DAMAGES CLAIMS

The Court of Appeals rested its decision on § 360k(a) of the MDA, which in relevant part prohibits any State from "establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). If one thing is clear from this language, it is that § 360k(a) does not *expressly* say anything about state-law tort or contract claims. As numerous statutes show, Congress knows how explicitly to pre-empt such claims when it wants to do so.[17] Only one portion of the MDA's legislative history pertains to this provision, and that fragment makes clear that § 360k(a) was

17 *See, e.g.*, 21 U.S.C. §§ 1715z-17(d), 1715z-18(e) (Domestic Housing and International Recovery and Financial Stability Act); 17 U.S.C. § 301(a) (Copyright Act of 1976); 29 U.S.C. § 1144(a), (c)(1) (ERISA).

meant to address positive enactments like state statutes and regulations.[18]

Pre-emption cannot be somehow inferred from § 360k(a). That provision uses the word "requirement" three times. Only in the context of state-law "requirements" is the term even arguably ambiguous; in the other two instances, it is clear that Congress contemplated positive enactments like statutes and regulations, not common-law actions.[19]

Other features of § 360k(a) reinforce the conclusion that it has limited pre-emptive effect. The provision addresses state-

18 The House Report stated:

> The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.... In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the requirement that intrauterine devices are subject to premarket approval in California.
>
> Because there [are] some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation, the reported bill authorizes a State or political subdivision thereof to petition the Secretary for exemptions from the bill's general prohibition on non-Federal regulation.
>
> H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976).

19 *See* 21 U.S.C. § 360k(a)(1) (referring to "any *requirement* applicable under this Act"); *id.* at § 360k(a)(2) (referring to "a *requirement* applicable to the device under this Act").

law requirements "with respect to a device." Webster's New Collegiate Dictionary defines "respect" as "a relation to or concern with something usually specified" and defines "respecting" as "in view of" and "with regard to."[20] The common law of torts does not have any specified relationship with "a device," nor was it developed in view of or with regard to "a device." Therefore, if the phrase "with respect to a device" is to be given its plain dictionary meaning — and if this Court is to remain faithful to the tenets of federalism that underlie pre-emption doctrine — the common law and other generally applicable forms of state law do not qualify as requirements "with respect to a device." *Cf. New York Conference of Blue Cross & Blue Shield Plans*, 115 S. Ct. at 1677 ("If 'relate to' were taken to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for '[r]eally, universally, relations stop nowhere.' But that, of course, would be to read Congress's words of limitation as mere sham, and to read the presumption against pre-emption out of the law whenever Congress speaks to the matter with generality.") (citation omitted).

The decisions of this Court have often drawn a significant distinction between pre-emption of specially targeted laws and pre-emption of generally applicable, background legal norms not directed at specific conduct in particular. In *Cipollone*, for example, a plurality of this Court held that federal law would not displace liability for fraud, and conspiracy to misrepresent or conceal material facts, because such liability is predicated "on a more general obligation — the duty not to deceive." 505 U.S. at 528–29. In *New York Telephone Co. v. New York State Dept. of Labor*, 440 U.S. 519, 533 (1979), a plurality explained that congressional pre-emption of state power to "enforce...general laws is more difficult to infer than intent to pre-empt laws directed specifically at concerted activity." In *United Steelworkers of America v. Rawson*, 495 U.S.

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20 Webster's New Collegiate Dictionary 986 (1977).

362, 371 (1990), this Court distinguished, for purposes of labor-law pre-emption, between duties imposed on a labor union by a collective bargaining agreement and generally applicable obligations, such as "the duty of reasonable care owed to every person in society." And in *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88 (1992), this Court held that the federal Occupational Safety and Health Act of 1970 pre-empts only state law that "constitutes, in a direct, clear, and substantial way, regulation of worker health and safety" and does not pre-empt "state laws of general applicability (such as laws regarding traffic safety or fire safety)," despite their demonstrable effect on occupational safety. *Id.* at 107 (internal quotations omitted).

The structure of the MDA provides further indication that the statute does not pre-empt state-law damages claims. A State may petition the Secretary of Health and Human Services for an exemption from the statute's pre-emptive effects, strongly suggesting that Congress had in mind state legislation and administrative rules. 21 U.S.C. § 360k(b). As one court put it, "if the term 'requirement' were interpreted so as to include tort law, the exemption procedures would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of [a] tort plaintiff?" *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989).

Furthermore, the section of the MDA relating to recall of harmful devices provides that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law" and prescribes rules for the calculation of economic losses to plaintiffs. 21 U.S.C. § 360h(d). Hence, Congress believed that a company's compliance with an FDA recall order — a form of a federal requirement — would not bar tort claims against it. Congress would not have needed to eliminate this defense had it intended the MDA to pre-empt state tort law. This being so, the MDA hardly reflects the requisite "unambiguous con-

gressional mandate to that effect." *Florida Lime & Avocado Growers, supra*, 373 U.S. at 147.

For all these reasons, *amici* submit that the MDA does not pre-empt state-law damages claims.

II. AT A MINIMUM, THE SECTION 510K PROCESS DOES NOT PRE-EMPT CLAIMS INVOLVING MEDICAL DEVICES THAT HAVE NOT RECEIVED FDA PREMARKET APPROVAL

As noted in the opinion below, the pacemaker was two steps removed from any federal evaluation of its safety and fitness. The pacemaker was approved as a device equivalent to another pacemaker, which was already on the market and which had been grandfathered under the MDA. 56 F.3d at 1340. Even if the MDA's pre-emptive effect extended to *some* state-law damages claims, the claims before this Court would not be pre-empted. Like *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995), this case involves the principle that there can be no pre-emption in the absence of a specific federal safety requirement. *See also Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985).

The Court of Appeals correctly concluded that medical devices entering the market through the "substantial equivalence" procedure of § 510k of the Act, 21 U.S.C. § 360e(b)(1)(B), are not subject to a specific requirement for pre-emption purposes. For a device to qualify as the "substantial equivalent" of one which is already being marketed, the FDA must determine that the new device has the same intended use as the predicate device and *either* the same technological characteristics *or* the same safety and effectiveness as the predicate device. § 360c(I)(1)(A).

Therefore, the Court of Appeals correctly determined that manufacturers of such devices cannot claim the shield of the MDA to displace state tort law because "[t]he 510(k) process is focused on *equivalence*, not safety" and "510(k) approval under the MDA, standing alone, is not a finding of safety and

effectiveness and does not impose specific requirements on a device for preemption purposes." Pet. App. 27a. The FDA has declared that its acceptance of a claim of "substantial equivalence" does "not in any way denote official approval of the device." 21 C.F.R. § 807.97.

As Congress has noted, the sheer volume of devices entering the market through the § 510(k) procedure prevents the FDA from rigorously scrutinizing each device. "[O]ver 80 percent of the devices that are potentially the most dangerous (Class III) enter the market on the basis of a claim by the manufacturer that they are 'substantially equivalent' to a device already on the market." H.R. Rep. No. 808, 101st Cong., 2d Sess. 1990, *reprinted in* 1990 U.S. Code Cong. & Admin. News 6307. In strengthening the MDA in 1990, Congress documented the practical problems confronting the FDA in verifying such claims and found that "the FDA has experienced difficulties in learning about serious problems with devices." *Id.* Accordingly, Congress cautioned that 510(k) approval "is not equivalent to an approval by the FDA of the device's safety and effectiveness." *Id.*

CONCLUSION

The judgment of the Court of Appeals should be reversed in part insofar as it holds that the MDA pre-empts any state-law damages claims.

Respectfully submitted,

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OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,
v.
LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS AMICUS CURIAE IN SUPPORT OF PETITIONER MEDTRONIC

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44

TABLE OF CONTENTS

Page

INTEREST OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT 1

ARGUMENT 4

I. THE EXPRESS LANGUAGE AND LEGISLATIVE HISTORY OF THE MEDICAL DEVICE AMENDMENTS REFLECT CONGRESS'S INTENT TO PREEMPT TORT SUITS 4

A. In Enacting the Medical Device Amendments, Congress Struck a Careful Balance To Ensure the Safety and Availability of Medical Devices 4

B. Congress Expressly Preempted State Efforts To Add to the FDA's Requirements. 7

II. THE COURT MUST GIVE EFFECT TO THE MDA'S PLAIN LANGUAGE MANDATING PREEMPTION 8

A. The Plain Meaning of the Term "Requirement" in the MDA Includes Requirements Imposed by State Courts 9

B. Section 360k Uses the Term "Requirement" Consistently To Include State Common Law Actions 13

C. State Courts Can "Establish" Requirements in Common Law Tort Actions 14

Page

D. The Absence of the Term "State Law" in Section 360k Does Not Limit the Preemptive Reach of the Provision 15

E. Section 360k Preempts More Than State Requirements Specifically Targeted at Medical Devices 16

F. The Remedies Provision of the MDA Does Not Suggest Any Limitation on the Preemptive Reach of Section 360k 20

III. PREEMPTION OF COMMON LAW CLAIMS IS NECESSARY TO EFFECTUATE THE PURPOSE OF THE MDA 22

IV. THE MDA PREEMPTS CLAIMS BASED ON FEDERAL REGULATIONS 24

V. THE MDA PREEMPTS PUNITIVE DAMAGES CLAIMS 28

CONCLUSION 30

TABLE OF AUTHORITIES

Page

Cases:

Anguiano v. *E.I. DuPont De Nemours & Co., Inc.*, 44 F.3d 806 (9th Cir. 1995) 12

Brown v. *Superior Court*, 751 P.2d 470 (Cal. 1988) 23

CSX Transp., Inc. v. *Easterwood*, 113 S. Ct. 1732 (1993) 9, 20

Chevron U.S.A., Inc. v. *Natural Resources Defense Council*, 467 U.S. 837 (1984) 3, 19

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Coleman v. *Thompson*, 501 U.S. 722 (1991) 14

District of Columbia v. *Greater Washington Bd. of Trade*, 113 S. Ct. 580 (1992) 17

FEC v. *National Conservative Political Action Comm.*, 470 U.S. 480 (1985) 25

Gertz v. *Robert Welch, Inc.*, 418 U.S. 323 (1974) . . . 29

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Table of Authorities Continued

Page

Haudrich v. *Howmedica, Inc.*, 642 N.E.2d 206 (Ill. App. 1994), *aff'd on other grounds*, 1996 WL 19012 (Ill. Jan. 18, 1996) 14

Hawaiian Airlines, Inc. v. *Norris*, 114 S. Ct. 2239 (1994) 9

Ingersoll-Rand Co. v. *McClendon*, 498 U.S. 133 (1990) 17, 18

Kemp v. *Pfizer, Inc.*, 835 F. Supp. 1015 (E.D. Mich. 1993) 23

Kennedy v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) 12, 13, 16, 18, 20

King v. *Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) 7

Mendes v. *Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) 7

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Table of Authorities Continued

Page

New York State Conference of Blue Cross & Blue Shield Plans v. *Travelers Ins. Co.*, 115 S. Ct. 1671 (1995) 18

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Silkwood v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984) 29

Smith v. *Wade*, 461 U.S. 30 (1983) 29

Talbott v. *C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed* (U.S. Feb. 16, 1996) (No. 95-1321) 27, 28

Texas State Teachers Ass'n v. Garland Indep. Sch. Dist., 489 U.S. 782 (1989) 14

United States Dep't of Treasury v. *Fabe*, 113 S. Ct. 2202 (1993) 25

West v. *American Telephone & Telegraph Co.*, 311 U.S. 223, 236 (1940) 14

Constitutions and Statutes:

U.S. Const. Art. VI, cl. 2 8

Airline Deregulation Act, 49 U.S.C. § App. § 1305(a)(1) 18

Table of Authorities Continued

Page

Consumer Product Safety Act, 15 U.S.C. § 2075(a) . . 26

Employee Retirement Income Security Act,
29 U.S.C. § 1144(a) 17, 18

Federal Boat Safety Act, 46 U.S.C. § 4306 25

Federal Food, Drug and Cosmetic Act,

21 U.S.C. §§ 301-395 4

21 U.S.C. § 331(a) 29

21 U.S.C. § 333(a) 29

21 U.S.C. § 333(f)(1)(A), (B) 29

21 U.S.C. § 334(a)(2) 29

21 U.S.C. § 337(a) 7

21 U.S.C. § 343-1 26

21 U.S.A. § 351 4

21 U.S.C. § 351(h) 26

21 U.S.C. § 352(a) 26

21 U.S.C. § 360 (k) 5

21 U.S.C. § 360c *et seq*. 1

21 U.S.C. § 360c(a) 5

21 U.S.C. § 360d(a)(2)(B) 5

21 U.S.C. § 360f 29

21 U.S.C. § 360h 20, 21

Table of Authorities Continued

Page

21 U.S.C. § 360h(a)-(b) 21

21 U.S.C. § 360h(d) 21

21 U.S.C. § 360h(e)(1) 29

21 U.S.C. § 360i 5

21 U.S.C. § 360k . . . . . *passim*

21 U.S.C. § 360k(a) . . . . . *passim*

21 U.S.C. § 360k(a)(2) 17, 19

21 U.S.C. § 360k(b) 8, 21

21 U.S.C. § 360ss 25

21 U.S.C. § 374(a) 5

National Traffic & Motor Vehicle Safety Act,
49 U.S.C. § 30103(b) 25

Poison Prevention Packaging Act,
15 U.S.C. § 1476(a) 26

Public Health Cigarette Smoking Act of 1969,
15 U.S.C. § 1334(b) 2, 10, 11, 13, 14, 15

Me. Rev. Stat. Ann. tit. xiv, § 221 22

S.C. Code Ann. § 15-73-10 22

Table of Authorities Continued

Page

Regulations:

21 C.F.R. § 808.1(b) 3, 19

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Legislative Materials:

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Page

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INTEREST OF AMICUS CURIAE

The Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit corporation with 114 corporate members from a broad cross-section of American industry, and the product liability lawyers who represent them. Its corporate members include manufacturers and sellers in industries ranging from electronics to automobiles to pharmaceutical products and medical devices.[1] PLAC's purpose is to file *amicus* briefs on behalf of its members on issues that affect the law of product liability. PLAC has submitted many *amicus* briefs in state and federal courts, including this Court.

In this case, the United States Court of Appeals for the Eleventh Circuit ruled that the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act expressly preempt certain state common law tort claims involving medical devices. PLAC is well-situated to address this issue. Its members often have confronted conflicting or duplicative obligations imposed by federal regulatory agencies and by state courts in product liability cases. PLAC therefore can offer a useful perspective on why uniform national standards governing medical products are important and how layers of regulatory burdens and litigation costs can impede innovation of lifesaving technologies.[2]

SUMMARY OF ARGUMENT

In adopting the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* ("MDA"), Congress fashioned a carefully calibrated, nationwide scheme of regulation by the Food and Drug Administration ("FDA"). The MDA was structured to protect the public from unsafe medical products *and* from barriers that excessive or conflicting state and federal burdens might erect to the availability of new, useful devices.

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[1] A list of PLAC's corporate members appears in the appendix hereto.

[2] The parties' written consent to the submission of this brief is on file with the Court.

Congress thus struck a delicate balance to avoid both overregulation and underregulation of medical devices, recognizing that either would undermine public health.

To maintain that balance, Congress explicitly barred states from imposing any requirement related to the safety or effectiveness of medical devices, which differs from or adds to the requirements applicable under the Act. 21 U.S.C. § 360k(a). Congress specifically sought to avoid overlapping layers of requirements imposed by individual states, including the unpredictable and often massive burdens inflicted through common law damage actions.

The Lohrs nonetheless contend that Section 360k(a) of the MDA preempts only requirements decreed by state statutes or regulations, and not those imposed by common law standards. This Court rejected that argument with respect to the parallel — indeed, narrower — preemption provision at issue in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992). The Public Health Cigarette Smoking Act of 1969 preempted any "requirement or prohibition . . . imposed under State law" based on smoking and health. 15 U.S.C. § 1334(b). The Court found that rulings under state tort law impose "requirements." 505 U.S. at 521. Since then, nine U.S. Courts of Appeals have concluded that the word "requirements" in Section 360k(a) means the same thing it did in *Cipollone*. The Lohrs' strained interpretations of the MDA — their suggestions that common law courts do not, in the words of Section 360k(a), "establish or continue in effect" legal rules and that the context of Section 360k confers a different meaning on "requirement" than in the Smoking Act — yield no different conclusion here.

In particular, there is no basis for the Lohrs' claim that Section 360k does not preempt any state law requirement,

including any tort law standard, that happens to cover other products in addition to medical devices. The Lohrs rely not on the language of Section 360k(a) itself, but rather on an FDA regulation stating that the statute "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices . . . ." 21 C.F.R. § 808.1(d)(1). Section 360k nowhere excludes from preemption state requirements of "general applicability." As this Court recognized in *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), such an exception would create "an utterly irrational loophole" because "there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute." *Id.* at 386 (citation omitted). If the regulation were to be interpreted as the Lohrs contend, it would impermissibly conflict with the statutory mandate. *See Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-44 & n.9 (1984).

In any event, the FDA regulation does not classify common law damage actions as "requirements of general applicability." Indeed, the regulation explicitly provides that state requirements established by "court decision" may be preempted. 21 C.F.R. § 808.1(b). By contrast, when identifying "State or local requirements of general applicability," the regulation omits court decisions from the list. *Id.* § 808.1(d)(1).

The Lohrs are equally wrong in arguing that a common law action alleging violation of FDA standards does not impose requirements "in addition to or different from" those applicable under the MDA, but rather merely enforces the federal requirements. A common law tort standard predicated on violation of FDA rules would require regulated companies to

pay damages, in addition to satisfying any monetary or injunctive requirements imposed by the FDA. The damages requirement would differ from and add to the requirements in the MDA, for the MDA incorporates no private right of action and imposes no duty to compensate patients for alleged personal injuries. Moreover, Congress considered excluding from preemption state laws that replicated federal standards. *See* S. 510, 94th Cong., 1st Sess. § 704 (1975). It chose not to retain such an exclusion in the MDA.

ARGUMENT

I. THE EXPRESS LANGUAGE AND LEGISLATIVE HISTORY OF THE MEDICAL DEVICE AMENDMENTS REFLECT CONGRESS'S INTENT TO PREEMPT TORT SUITS

A. In Enacting the Medical Device Amendments, Congress Struck a Careful Balance To Ensure the Safety and Availability of Medical Devices

When enacted in 1938, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-395, scarcely touched on regulation of medical devices. *See id.* § 351 (addressing adulterated and misbranded devices). But as technology advanced and doctors relied increasingly on medical devices, Congress recognized the need for comprehensive regulation. *See generally* S. Rep. No. 33, 94th Cong., 1st Sess. 2-7 (1975) ("Senate Report"). It therefore enacted the Medical Device Amendments of 1976.

The MDA reflects a careful balancing of the public interest in the safety and effectiveness of medical devices on the one hand, and the development and availability of medical devices on the other. As discussed below, Congress determined that preserving this balance of interests necessitated preemption of state law claims such as those raised by the Lohrs.

In the MDA, Congress prescribed detailed statutory requirements for, among other things,

- premarketing reports to the FDA, 21 U.S.C. § 360(k);
- classification of devices as Class I, II, or III, depending on the extent of regulatory controls needed for a "reasonable assurance of the safety and effectiveness of the device," 21 U.S.C. § 360c(a);
- regulatory mandates adopted by the FDA when needed to provide "reasonable assurance of [the device's] safe and effective performance," governing the construction, components, ingredients, properties, testing or labeling of the device, 21 U.S.C. § 360d(a)(2)(B);
- expanded FDA inspections of company facilities, 21 U.S.C. § 374(a); and
- reports to the FDA, 21 U.S.C. § 360i.

Congress recognized both the importance of these requirements to public health and safety and the chilling effect of excessive or conflicting burdens on a dynamic, creative industry. The Senate Report on the MDA reveals Congress's concern about the potential for overregulation to stymie innovation. The Report notes, for example:

> the testimony of a number of witnesses . . . who expressed concern about the impact of this legislation on the small manufacturer of medical devices. The concern stemmed from the importance of the small innovative manufacturer in the invention and development of new medical devices and the inability of these firms, because of limited financial resources, to sustain the high level of administrative costs demanded of a highly regulated industry. . . . The Committee is confident that the administration of this new

> law will take into account the need to preserve the small manufacturer's role in the device industry.

Senate Report at 18.

The corresponding House Report voices the same concern. It cites the views of the Study Committee that originally proposed the MDA regarding the need to protect consumers from dangerous or useless products while not impeding development of lifesaving medical devices:

> Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field.

H.R. Rep. No. 853, 94th Cong., 2d Sess. 10 (1976) ("House Report"). Taking these views into consideration, the House Committee concluded that its bill accommodated both objectives and

> developed a *balanced* regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions.

Id. at 12 (emphasis supplied).

To achieve this equilibrium and avoid both underregulation and overregulation, Congress made the FDA's classification of devices as Class I, II, or III hinge on the level of regulatory controls reasonably necessary to assure safety and efficacy. *See* H.R. Rep. No. 1090, 94th Cong., 2d Sess. 55-56 (1976) ("The extent of regulation under each class to provide

reasonable assurance of safety and effectiveness varies with each class . . . ."). In other words, for each device, the FDA has a statutory responsibility to calculate the appropriate level of regulation to ensure reasonable safety and effectiveness, without prescribing requirements that could unduly hinder development of lifesaving technologies. In fashioning this regulatory structure, Congress entrusted the FDA with exclusive authority not only to impose stringent controls on medical devices, but also to refrain from imposing overly stringent controls, as needed to attain this delicate balance.

B. Congress Expressly Preempted State Efforts To Add to the FDA's Requirements

Congress recognized that, in order to preserve the lines drawn by the FDA and avoid overregulation, it was necessary to foreclose others from imposing additional or differing requirements. *See King* v. *Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir.) (Aldrich, J. and Campbell, J., concurring), *cert. denied,* 114 S. Ct. 84 (1993). Simply put, it would have made no sense to mandate that the FDA carefully calibrate the level of regulation to achieve the optimal balance for each device, but then allow each of the fifty states to double or treble the burdens on manufacturers. Indeed, the House Report on the MDA explicitly states that "if a substantial number of differing requirement[s] applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." House Report at 45.

Accordingly, Congress created no private right of action under the MDA, precluding individual litigants from interfering with the FDA's regulatory agenda. The FDA has exclusive authority to enforce the statute. 21 U.S.C. § 337(a). *See also Mendes* v. *Medtronic, Inc.*, 18 F.3d 13, 19 n.4 (1st Cir. 1994)

("Congress did not intend to create a private right of action . . . .").

More importantly, Congress included in the MDA language expressly preempting state requirements on medical devices. The MDA provides that:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any requirement* —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis supplied). Thus, any state requirement is preempted if it (i) relates to the safety or effectiveness of a medical device; and (ii) differs from or adds to a requirement applicable under the MDA.[3] Unlike statutory schemes providing minimum federal standards that states may supplement, the MDA fixes the level of regulation for medical devices and bars states from tacking on any other requirement.

II. THE COURT MUST GIVE EFFECT TO THE MDA'S PLAIN LANGUAGE MANDATING PREEMPTION

Under the Supremacy Clause, U.S. Const. art. VI, cl. 2, the congressional power to legislate includes the power to displace

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[3] To allow the FDA to fine-tune the regulatory balance even further, Congress afforded the Agency authority under specified conditions to promulgate regulations exempting from preemption certain state requirements for medical devices. *See* 21 U.S.C. § 360k(b).

state laws that would interfere with congressional objectives or undermine the uniformity of federal law. As this Court has repeatedly emphasized, whether a federal statute exercises that power depends on Congress's intent. *Cipollone*, 505 U.S. at 516; *Hawaiian Airlines, Inc.* v. *Norris*, 114 S. Ct. 2239, 2243 (1994). Where, as here, the statute expressly mandates preemption, there can be no doubt that Congress intended to preempt state law. The question is not whether the MDA overrides state law, but to what extent. *See, e.g., Cipollone*, 505 U.S. at 545 (Scalia, J., concurring in the judgment in part and dissenting in part).

To determine the preemptive reach of the MDA, this Court must "'begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.'" *Morales*, 509 U.S. at 383 (quoting *FMC Corp.* v. *Holliday*, 498 U.S. 52, 56 (1990)). In particular, the Court "must give effect" to the "plain language [of the preemption provision] unless there is good reason to believe Congress intended the language to have some more restrictive meaning." *Cipollone*, 505 U.S. at 521 (plurality) (citations omitted); *see also id.* at 544-56 (Scalia, J., concurring in the judgment in part and dissenting in part); *see also CSX Transp., Inc.* v. *Easterwood*, 113 S. Ct. 1732, 1737 (1993) (plain wording of statute is best evidence of congressional intent to preempt).

A. The Plain Meaning of the Term "Requirement" in the MDA Includes Requirements Imposed by State Courts

The language of Section 360k(a) barring states from imposing "any requirement" different from or in addition to those under the MDA encompasses requirements imposed by state tort law. This Court held in *Cipollone* that "requirement"

or "prohibition" included common law tort rules. 505 U.S. at 521. The federal statute at issue in *Cipollone*, the Public Health Cigarette Smoking Act of 1969 ("Smoking Act"), contained an express preemption provision similar to Section 360k(a), though it contained limitations not included in the MDA provision:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

15 U.S.C. § 1334(b).

The Court held that common law damages actions impose "requirements" and "prohibitions" subject to preemption under this provision. Any contrary approach, in the Court's view, conflicted "*both* with the plain words of the [Smoking] Act *and* with the general understanding of common law damage actions." 505 U.S. at 521 (emphasis supplied). As to the expansiveness of the Act's preemption provision, the Court held:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."

Id. (quoting *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)). Further, elaborating on the

"general understanding of common law damages actions," the Court observed that they "are premised on the existence of a legal duty and it is difficult to say that such actions do not impose 'requirements or prohibitions.'" 505 U.S. at 522.[4]

Section 360k(a) of the MDA sweeps at least as broadly as the provision that preempted common law claims in *Cipollone*. The MDA directs that "no State or political subdivision of a State may establish or continue in effect . . . any requirement" different from or in addition to those imposed under the MDA. 21 U.S.C. § 360k(a). This Court's interpretation of "requirement" in *Cipollone*, and its delineation of the reach of the preemption provision using that term, apply equally to this case. The principal difference between Section 360k(a) and the preemption provision in the Smoking Act is purely one of style: Congress used the active voice in the MDA, and the passive voice ("no requirement . . . shall be imposed under State law") in the Smoking Act.[5] This subtlety is inconsequential. Under both provisions, the actor — the party imposing or establishing a requirement — is necessarily the State, and the medium through which it acts is necessarily state law. There is no basis in the statutory text or structure to conclude that Congress intended to make the same word, "requirement," mean different things in these parallel statutory settings.

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[4] Justices Scalia and Thomas specifically agreed with the plurality on this issue, providing a majority of six Justices. *Cipollone*, 505 U.S. at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part).

[5] The Smoking Act also contained limitations on preemption which were more restrictive than Section 360k, *i.e.*, that the requirement or prohibition be "based on smoking and health" and that it pertain to "advertising or promotion" of cigarettes.

Moreover, the "general understanding of common law damages actions" has not changed in the four years since *Cipollone* was decided. Such actions remain premised now, as they were then, on the existence of a legal duty. They continue to impose requirements. *See* Restatement (Second) of Torts § 4 (1965) ("the word 'duty' is used throughout the Restatement of this Subject to denote the fact that the actor is required to conduct himself in a particular manner"); § 402A cmt. h (seller "may be required to give adequate warning"); W. Prosser & W.P. Keeton, *Prosser and Keeton on Torts* 22 (5th ed. 1984) (tort liability is based on "a departure from the conduct required of the actor by society for the protection of others"). The contention that common law damage actions are only compensatory and not regulatory lacks any vitality after *Cipollone*.[6]

Applying *Cipollone*, nine U.S. courts of appeals have held in at least 17 opinions that Section 360k(a) preempts state common law tort suits. The Lohrs rely on one errant court of appeals decision that conflicts even with precedent in the same Circuit, *compare Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *with Anguiano* v. *E.I. DuPont De Nemours &*

[6] In *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), the court of appeals cited the *dissenting opinion* in *Cipollone* for the proposition that damages actions are merely compensatory and impose no requirements because "manufacturers facing common law challenges retain the discretion whether to alter their product or . . . bear the cost of any lawsuits that might result from their decision." *Id.* at 1459. Reliance on that dissent signals the court of appeals' deviation from the current state of the law.

Co., Inc., 44 F.3d 806 (9th Cir. 1995), to dispute that authority.[7] Their arguments are untenable.

B. Section 360k Uses the Term "Requirement" Consistently To Include State Common Law Actions

The Lohrs first contend that the word "requirement" is used differently in the MDA, where it appears three times, than in the Smoking Act, where it appears only once. Focusing on the repetition of "requirement" in Section 360k(a), the Lohrs contend that internal consistency demands an interpretation of the term confined to statutory or regulatory mandates. Brief of Cross-Petitioners ("C-Pet. Brief") at 18-19.

The reasoning behind this claim is somewhat tortured: the word "requirement," when used in Section 360k(a) to identify the federal provisions with preemptive effect, embraces only mandates "applicable . . . under this chapter" — which necessarily are imposed by federal statute or FDA regulation. Therefore, the Lohrs assert, when applied to preempted state actions, the term must again be limited to statutory and regulatory prescriptions. The Lohrs' premise is that "requirement" must have the same meaning wherever it is used.

In fact, the meaning of "requirement" does remain constant throughout Section 360k. It is only the context that changes. A "requirement applicable" under the MDA necessarily stems

[7] The Ninth Circuit is the *only* court of appeals to hold that Section 360k(a) does not preempt state common law claims. The court reached that conclusion in *Kennedy* only after retracting its own reasoning in *Anguiano* that, in promulgating the MDA, Congress expressly intended to preempt state tort law. *See Kennedy*, 67 F.3d at 1457 n.1. The court acknowledged that its new decision was inconsistent with the holdings of the other courts of appeals that have addressed the issue. *Id.* at 1458.

from that statute or is embodied in an FDA regulation or other Agency action under it. There is no applicable federal common law. By contrast, the preempted state or local "requirements" can derive from statutes, regulations, or common law rules. "Requirement" thus means precisely the same thing throughout Section 360k. It is defined by the existence of compulsion, not by who or what does the compelling. *See, e.g., Webster's New World College Dictionary* (3d ed. 1996) (defining "requirement" as "something obligatory or demanded").

C. State Courts Can "Establish" Requirements in Common Law Tort Actions

The Lohrs also suggest that, even if courts "impose" requirements in common law damages actions within the meaning of the Smoking Act, they do not, as a matter of ordinary parlance, "establish or continue in effect" such requirements, as the MDA provides. The Illinois Court of Appeals, cited by the Lohrs, framed the argument succinctly: "Case law is handed down, developed, or decreed, but it is not 'established or continued in effect.'" *Haudrich* v. *Howmedica, Inc.*, 642 N.E.2d 206, 210 (Ill. App. 1994), *aff'd on other grounds*, 1996 WL 19012 (Ill. Jan. 18, 1996).

This argument improperly constricts the meaning of common terms. Court opinions, like statutes and regulations, *can establish* legal requirements, as this Court itself has repeatedly recognized. *See, e.g., Coleman* v. *Thompson*, 501 U.S. 722, 739 (1991) ("We can establish a per se rule that eases the burden of inquiry on the federal courts"); *Texas State Teachers Ass'n* v. *Garland Indep. Sch. Dist.*, 489 U.S. 782, 789 (1989) ("The Court then went on to establish certain principles to guide the direction of the lower courts in setting fee awards"); *West* v. *American Telephone & Telegraph Co.*, 311 U.S. 223, 236 (1940) ("the rules of decision established by

judicial decisions of state courts are 'laws' as well as those prescribed by statute") *Pickett* v. *Foster*, 149 U.S. 505, 530 (1893) ("decisions of the supreme court of Louisiana establish a rule of property binding on the federal courts"). Congress's choice of the word "establish" in the MDA rather than "impose" does not distinguish this case from *Cipollone*.

D. The Absence of the Term "State Law" in Section 360k Does Not Limit the Preemptive Reach of the Provision

The Lohrs contended in their cross-petition — though they prudently abandon the argument in their brief — that preemption under the MDA is more limited than under the Smoking Act because Section 360k does not refer to "state law" as the Smoking Act did. Cross-Petition ("C-Pet.") at 19. This contention is meritless.

In *Cipollone*, this Court held *first* that the words "requirement and prohibition" in the Smoking Act encompassed obligations imposed through state common law damages actions. It held *second* and independently that the phrase "state law" "include[s] common law as well as statutes and regulations." 505 U.S. at 521-22. Nothing in *Cipollone* suggests that the term "state law" has some talismanic significance — that to trigger preemption, Congress must employ both that term and the word "requirements." If this precise wording were necessary, Congress could not bar common law tort suits unless it recited word-for-word that "no state or political subdivision may establish or continue in effect, *through state law*, requirements or prohibitions." To insist on such a formulaic approach is nonsensical. The only way a state *can* "establish . . . requirements" is through state law. The redundancy that the Lohrs would mandate is an artificial barrier to effectuating Congress's clear objective — to prevent states

from imposing burdens, in whatever form, that upset the regulatory balance fashioned by the FDA for each device.

E. Section 360k Preempts More Than State Requirements Specifically Targeted at Medical Devices

Echoing the maverick Ninth Circuit decision in *Kennedy,* the Lohrs further contend that Section 360k(a) does not preempt their state law claims because it does not preempt state law requirements applicable to other products as well as medical devices. This contention appears to rely on the FDA's regulation providing that the MDA "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices . . . ." 21 C.F.R. § 808.1(d)(1).

This argument is flawed in many ways. To begin with, Section 360k nowhere refers to "requirements of general applicability." By its terms, the section bars states from establishing "with respect to a device" "*any* requirement" that adds to or differs from those imposed under the MDA. 21 U.S.C. § 360k(a). "Any" is not an ambiguous word. It does not mean "some." It certainly does not mean "of general applicability." The Lohrs have cited no decision of this Court that has ever given such a strange meaning to "any" in any context whatsoever.

Nor do the words "with respect to a device" exclude requirements that also apply to other products in addition to devices. That language says that the state requirement must cover devices, not that it must encompass *only* devices and exclude other products.

Similarly, no limitation on preemption for laws of general applicability arises from the statutory provision that the preempted requirement "relate[ ] to the safety or effectiveness

of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C § 360k(a)(2). A broad rule regarding safety that applies to a medical device as well as other products relates to the safety of that device, every bit as much as a rule that addresses the particular device and no others. In *Ingersoll-Rand Co.* v. *McClendon,* 498 U.S. 133 (1990), the Court considered whether ERISA preempted an employee's claim in a tort and contract action that he was wrongfully discharged to avoid pension liability. The preemption provision of ERISA covered any state laws that "relate to any employee benefit plan." 29 U.S.C. § 1144(a). The Court noted that, as a matter of common sense, "a state law may 'relate to' a benefit plan, and thereby be preempted, even if the law is not specifically designed to affect such plans, or the effect is only indirect." 498 U.S. at 139. *See also District of Columbia* v. *Greater Washington Bd. of Trade,* 113 S. Ct. 580, 583 (1992) ("the ordinary meaning of 'relate to' . . . [is consistent with] 'deliberately expansive' language chosen by Congress") (citing Black's Law Dictionary 1288 (6th ed. 1990)). Here, too, a general duty of care may *relate to* the safety of a medical device even if the duty is not exclusively applicable to that device alone.

This Court's opinion in *Morales* also recognizes the breadth of the term "relate to" in a preemption provision. In *Morales,* the Court noted that the "ordinary meaning of these words is a broad one — 'to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with,' Black's Law Dictionary 1158 (5th ed. 1979) — and the words thus express a broad preemptive purpose." 504 U.S. at 383. At issue in *Morales* was the provision in the Airline Deregulation Act prohibiting states from enforcing any law "relating to rates, routes or services of

any air carrier." 49 U.S.C. App. § 1305(a)(1). The Attorney General of Texas argued, as the Lohrs contend here, that only state laws specifically addressed to the airline industry were preempted. The Court found that argument specious: "Besides creating an utterly irrational loophole (there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute), this notion similarly ignores the sweep of the 'relating to' language." 504 U.S. at 386.[8] A requirement that a manufacturer of a medical device adhere to a particular standard of care thus relates to safety whether that requirement is imposed through tort laws applicable to other products, or through regulations directed only to that particular medical device.

To the extent the FDA regulation suggests otherwise, it conflicts with the plain language of the MDA. Indeed, if the FDA regulation were so interpreted, it would misread the statute. The regulation explains that state and local requirements of general applicability, along with certain other

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[8] The Court of Appeals in *Kennedy* ignored *Morales* and *Ingersoll-Rand* and instead cited *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 115 S. Ct. 1671 (1995), to limit Section 360k. But *Travelers* is inapposite. It involved a state law that imposed a surcharge on health insurance. Because employee benefit plans purchase health insurance, the petitioner argued that the law "relate[d] to . . . employee benefit plan[s]" and was preempted under ERISA, 29 U.S.C. § 1144(a), even though the state law imposed no standards of conduct on benefit plan administrators. This Court found the connection between the state law and benefit plan tenuous and peripheral. 115 S. Ct. at 1679. By contrast, a central purpose of common law tort actions is to enforce standards of conduct regarding safety. To find that those suits "relate to" the safety of a medical device does not, by any measure, stretch that term.

requirements, are "not preempted by section 521(a) of the act [Section 360k(a)] because they are not 'requirements applicable to a device' within the meaning of" Section 360k(a). 21 C.F.R. § 808.1(d). But Section 360k(a) uses the phrase "requirement *applicable to the device*" only when describing requirements imposed under federal law. 21 U.S.C. § 360k(a)(2) (emphasis supplied). As to state requirements, the statute is, if anything, broader, providing that no state may establish or continue in effect "*with respect to* a device . . . *any* requirement." *Id.* § 360k(a) (emphasis supplied). Thus, the FDA's rationale for excusing state requirements of general applicability from preemption — that they are not "applicable to a device" — is inconsistent with the plain language of the MDA and is entitled to no deference. *See Chevron,* 467 U.S. at 843 & n.9.

Even if Section 360k could properly be construed to preclude preemption of state "requirements of general applicability," the FDA's regulation reflects that the Agency does not include common law damage actions within that category. When paraphrasing the statute, the regulation provides that "no State or political subdivision of a State may establish or continue in effect any requirement . . . (whether established by statute, ordinance, regulation, or *court decision*) . . . ." 21 C.F.R. § 808.1(b) (emphasis supplied). Conversely, when identifying various requirements of "general applicability," the regulation omits court decisions and cites only statutes and ordinances, such as the Uniform Commercial Code and general electrical codes. 21 C.F.R. § 808.1(d)(1). *See Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1277 (7th Cir. 1995) ("Section 808.1(d), listing various state requirements that are not preempted by the statute, is noticeably silent on the matter of state tort claims when read in its entirety."); *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 543 n.2 (3d Cir.), *cert.*

denied, 115 S. Ct. 429 (1994) ("Significantly, the list of requirements exempted from § 360k does not include state tort or common law claims."). The regulation is thus irrelevant to the issue before the Court.[9]

F. The Remedies Provision of the MDA Does Not Suggest Any Limitation on the Preemptive Reach of Section 360k

In the face of the clear language of Section 360k, the Lohrs look elsewhere in the statute for evidence that Congress did not mean what it said in that provision. That quest is suspect. As the Court held in *CSX Transportation, Inc.*, 113 S. Ct. at 1737, "the task of statutory construction must in the first instance focus on the plain wording of the [preemption] clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *See also Cipollone*, 505 U.S. at 517 (no need to look beyond express preemption provision); *Morales*, 504 U.S. at 385 (a "general 'remedies' saving clause cannot be allowed to supersede the specific substantive pre-emption provision").

Nonetheless, the Lohrs purport to find better evidence of congressional intent in 21 U.S.C. § 360h than in Section 360k, the express preemption provision. Section 360h provides that the FDA may order a company to notify doctors, hospitals and patients of unreasonable risks of a device, as well as to repair,

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[9] Concurring in the Ninth Circuit's ruling in *Kennedy*, Judge Reinhardt opined that the reference to "court decisions" in the regulation only covered those decisions based on a rule or regulation aimed specifically at medical devices. 67 F.3d at 1461. That interpretation does as much violence to the language of the regulation as the regulation, so interpreted, does to the language of the statute. As a matter of logic as well as the limitations on the judicial function, the only means by which a state court "establish[es]" a "requirement" is through common law adjudication.

replace or refund the purchase price of such a device. 21 U.S.C. §§ 360h(a)-(b). Section 360h(d) includes a limited saving clause:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

The Lohrs contend that this provision would not be necessary if state common law remedies were preempted. This contention is curious. The Lohrs' previously addressed arguments *overstated* the limitations in Section 360k. This line of reasoning *ignores* them. For one, a manufacturer might be subject to certain state law claims — and the saving clause of Section 360h would be potentially applicable — if a state went through the statutory procedures to obtain an FDA exemption from preemption for a particular requirement. *See* 21 U.S.C. § 360k(b). Moreover, as already noted, only state requirements related to the safety and effectiveness of a device or to some other requirement in the MDA are preempted. If, for example, the FDA were to order a recall of a device, the purchasers — often hospitals and physicians — might suffer an "economic loss" of the purchase price. Commercial claims for those losses may not necessarily establish requirements related to the safety or effectiveness of the device. Section 360h merely recognizes that the MDA may not in all circumstances encroach upon remedies for such commercial losses. Indeed, the focus in Section 360h(d) on "economic loss" indicates that such commercial transactions, rather than personal injury suits like this one, were what Congress had in mind.

III. PREEMPTION OF COMMON LAW CLAIMS IS NECESSARY TO EFFECTUATE THE PURPOSE OF THE MDA

Ultimately, all the Lohrs' strained readings of the statutory text and the regulatory provisions founder because they presume Congress acted illogically. Under a reading of Section 360k in which common law damage claims survive preemption but state statutes do not, the very same claims could be preempted in one state, but not in another, based on the happenstance of whether those claims rested on a common law rule or a state statute. Specifically, in a state that has adopted a product liability statute — and at least two states had done so by the time the MDA was enacted, *see* Me. Rev. Stat. Ann. tit. xiv, § 221 (adopted 1973); S.C. Code Ann. § 15-73-10 (adopted 1962) — a claim under that statute involving a medical device would be preempted, even if the state statute merely codified preexisting common law principles. But in a state with no such statute, the same claim would survive. Given Congress's express purpose in adopting the MDA to establish national uniformity in the regulation of medical devices, this result would be perverse. It makes no sense to suggest that a state may avoid preemption by including a requirement in a broad rule of common law rather than in a statute or regulation. Congress did not intend such an anomalous result.

What Congress did intend was that, for each device, the FDA gauge the level of regulation sufficient to ensure safety, while not unduly impeding innovation. Congress included a preemption provision to prevent states from subverting that intended balance. Particularly in light of that purpose, it is unreasonable to contend that Congress was concerned with the form, rather than the content and effect, of state requirements applicable to medical devices. The burdens on manufacturers

can be equally compounded, the uniformity of federal law equally impaired, and innovation equally stifled by "different or additional" state requirements, whether they are embodied in specific regulations, general statutes, or adjudication under the common law. *See, e.g., Kemp* v. *Pfizer, Inc.*, 835 F. Supp. 1015, 1023 (E.D. Mich. 1993) (describing how the preemption provisions of the MDA serve Congress's intent to alleviate "the fear and hesitancy in developing original and ground-breaking medical devices"); *Gile*, 22 F.3d at 546 ("state tort claims run counter to the important public policy, recognized by Congress, of promoting scientific inventions"); *Brown* v. *Superior Court*, 751 P.2d 470, 479 (Cal. 1988) (subjecting drug manufacturers to strict liability may discourage research and development of beneficial products); *see also* Louis Lasagna, "The Chilling Effect of Product Liability on New Drug Development," in *The Liability Maze* 334, 335 (Peter Huber and Robert Litan, eds., 1991) (burdens of defending against product liability suits are a serious disincentive to research and development of medical devices).

Indeed, as of 1996, some makers of raw materials for medical devices, because of liability concerns, have withdrawn from the market products that device manufacturers need. *See, e.g.*, 141 Cong. Rec. S1803 (daily ed. Jan. 31, 1995) (Statement of Sen. McCain) ("The cost of defending [product liability] suits often exceeds the profits generated by the sale of materials [and therefore] some manufacturers and suppliers have begun to cease supplying their products for use in permanently implanted medical devices."). And women in the United States can no longer buy *any* intrauterine device because of potential tort liability, although these products are used safely in other countries. Peter W. Huber, *Galileo's Revenge* 157, 183-84 (1991). Plainly, the burdens of litigation dwarf the state regulatory burdens that the Lohrs admit the statute

does preempt, and the former are far more unpredictable. In carefully fashioning a regulatory balance and preempting state laws to preserve it, Congress would have been reckless to have at the same time sheltered tort liability from any limitation. It did not do so.

IV. THE MDA PREEMPTS CLAIMS BASED ON FEDERAL REGULATIONS

The court of appeals below determined that the MDA preempts state tort law claims predicated on a violation of FDA standards. *Lohr* v. *Medtronic, Inc.*, Appendix to Petition in No. 95-754, at 13a-14a. That conclusion is correct. Any other result would disrupt the regulatory balance Congress struck in the MDA.

The Lohrs contend that a common law damages suit alleging a violation of the FDA standards does not impose requirements in addition to or different from those applicable under the MDA. Rather, they argue, such a suit merely enforces FDA's standards and therefore does not run afoul of Section 360k. This argument offends the plain meaning of the statute.

Even if predicated on a violation of FDA regulations or of the Federal Food, Drug & Cosmetic Act, a common law tort suit requires a regulated company to defend and potentially to pay damages for that violation. A requirement to pay damages is "different from or in addition to" the requirements in the MDA, for the MDA incorporates no private right of action and imposes no requirement to compensate patients for personal injuries. To reverse that congressional decision, to impose on regulated companies a requirement to pay damages — in addition to whatever recalls, refunds, or penalties the FDA might order and in addition to other regulatory costs the FDA regulations might impose — would create a new regulatory

balance detrimental to the innovation of important medical technologies.[10]

In fact, Congress considered and rejected a provision that would *not* have preempted state laws "identical to the Federal requirements." Such a provision appeared in the version of the MDA initially passed by the Senate. *See* S. 510, 94th Cong., 1st Sess. § 704 (1975). Congress's decision to drop that language and instead to preempt state requirements not only "different from," but also "in addition to," the MDA's requirements is conclusive. Indeed, to have any meaning, the words "in addition to" in Section 360k(a) must cover state requirements that are *not* different from those imposed under the MDA. *See, e.g., United States Dep't of Treasury* v. *Fabe*, 113 S. Ct. 2202, 2210 n.6 (1993) (each word of statute must be given meaning); *FEC* v. *National Conservative Political Action Comm.*, 470 U.S. 480, 486 (1985) (same).

Moreover, in other statutes, where Congress has intended to leave intact state laws that replicate federal standards, it has said so explicitly. *See, e.g.*, Radiation Control for Health & Safety Act, 21 U.S.C. § 360ss (no State or political subdivision may establish or continue in effect any standard "which is not identical to the Federal Standard"); National Traffic & Motor Vehicle Safety Act, 49 U.S.C. § 30103(b) (State may only prescribe or continue in effect a standard "identical to the standard prescribed under this chapter"); Federal Boat Safety Act, 46 U.S.C. § 4306 (State may not establish a standard "that

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[10] Because damages actions do not impose requirements identical to those in the MDA, the FDA's regulation indicating that Section 360k does not preempt "state or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act," 21 C.F.R. § 808.1(d)(2), is not applicable, even assuming it were consistent with the statute.

is not identical to a regulation prescribed under section 4302 of this title"); Poison Prevention Packaging Act, 15 U.S.C. § 1476(a) (same); Consumer Product Safety Act, 15 U.S.C. § 2075(a) (same); Nutritional Labeling and Education Act, 21 U.S.C. § 343-1 (same). In formulating the MDA, Congress specifically considered and omitted such language, which would have preserved identical state requirements.

As a practical matter, ruling that Section 360k does not preempt claims alleging violation of FDA standards would defeat the purpose of the provision. Many FDA requirements are quite general. For example, if the Court recognized a noncompliance exception to preemption, plaintiffs would charge in virtually every lawsuit involving an alleged failure to warn that the product labeling was "false and misleading" in violation of the Federal Food, Drug & Cosmetic Act. 21 U.S.C. § 352(a). Similarly, a case involving alleged manufacturing or design defects would likely charge that the product was adulterated. *See* 21 U.S.C. § 351(h). A complaint alleging *per se* negligence based on the violation of such a provision might well — under the noncompliance exception — survive a motion to dismiss, necessitating discovery and resulting in numerous settlements by manufacturers to avoid the cost of litigation and the risk of liability. This would raise the cost of medical devices and undermine innovation.

If such cases were to proceed, state courts and juries determining whether a violation of FDA standards had occurred would have to interpret those FDA requirements. They would have to assess the significance of the alleged violations and determine the relationship between the federal requirement that was allegedly violated and the alleged product defect giving rise to the tort claim. If the FDA had approved the product, or passed on its substantial equivalence to existing products, its

intended uses, its safety and its effectiveness, or (as often occurs) dictated the labeling, the state court would have to second-guess the Agency's decisions. If the plaintiff's theory were that the FDA had been defrauded or tricked into its decision, the Court would have to undertake a detailed examination of the FDA's decisionmaking process and determine whether and how the alleged fraud affected it. Sanctioning such inquiries would be a prescription for costly litigation that would impair the uniformity of federal regulation, invade the domain Congress assigned exclusively to the FDA, and skew the regulatory balance the MDA attempted to implement.

The Court of Appeals for the First Circuit in *Talbott* v. *Bard*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, No. 95-1321 (U.S. Feb. 16, 1996), recognized how an exception for claims based on FDA regulations would entangle state courts in the FDA's work:

> If state tort claims were allowed to go forward, a state court would initially have to determine whether the manufacturer had complied with the MDA. If, as in this case, the plaintiff claimed that the manufacturer had defrauded the FDA, the state court would need to determine whether the FDA had in fact been defrauded and whether the FDA would have approved the device absent the fraud. Under this scheme, a device manufacturer could potentially be subject to numerous inconsistent interpretations and applications of the MDA across different states, thus undermining the MDA's goal of uniformity. Moreover, if state courts erred in their application of the MDA, they would effectively be imposing requirements "different from, or in addition to" those imposed by federal law.

Id. at 29. *See also Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.) ("states have no authority to police [manufacturers'] compliance with the FDA's procedures"), *cert. denied,* 116 S. Ct. 67 (1995); *Reeves* v. *Acromed Corp.*, 44 F.3d 300, 307 (5th Cir.) ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress's expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers."), *cert. denied,* 115 S. Ct. 2251 (1995).

In short, to hold that damage claims alleging a violation of FDA standards are not preempted would permit state courts to duplicate the FDA's functions, defeating the purpose of granting the Agency exclusive authority to enforce the MDA and imposing burdens beyond those the Agency mandates. That was not Congress's intent.

V. THE MDA PREEMPTS PUNITIVE DAMAGES CLAIMS

The Lohrs have not asserted a claim for punitive damages, but the decision in this case could affect the issue. If the Court determines that common law tort actions for compensatory damages are preempted, it will follow *a fortiori* that claims for punitive damages are preempted as well. If, however, any of the Lohrs' tort claims withstand preemption, the Court should, for the reasons discussed below, expressly state that it is not deciding whether punitive damages claims survive preemption.

Cipollone, as noted above, expunged any argument that the purpose of tort actions is merely compensatory and not regulatory. That argument is even weaker with respect to punitive damages awards. The primary purpose of punitive damages is to regulate conduct, not to compensate victims. Punitive damages are "private fines levied by civil juries."

Gertz v. *Robert Welch, Inc.*, 418 U.S. 323, 350 (1974). *See Smith* v. *Wade,* 461 U.S. 30, 49 (1983) ("deterrence of future egregious conduct is a primary purpose . . . of punitive damages").[11]

In using punitive damages awards to punish manufacturers of medical devices for developing defective products, states impose requirements that are different from and in addition to the MDA's nationally uniform punitive sanctions applicable to adulterated or misbranded devices. The FDA may seek from any person who violates a requirement of the MDA civil penalties of up to $15,000 per violation, and $1 million per proceeding. 21 U.S.C. § 333(f)(1)(A), (B). The FDA may also initiate a criminal prosecution when a manufacturer markets an adulterated or misbranded device. *Id.* §§331(a), 333(a). Moreover, such a device is subject, at the FDA's initiative, to seizure and forfeiture, *id.* § 334(a)(2), recall, § 360h(e)(1), or a total ban. *Id.* § 360f. A requirement in a state suit to pay punitive damages clearly differs from and adds to these punishments. Whatever conclusion the Court reaches as to preemption of tort suits involving medical devices in general, punitive damages claims clearly are preempted.

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[11] *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), does not militate against preemption of punitive damages claims. In *Silkwood,* the Court held that the Atomic Energy Act did not *impliedly* preempt state tort law, including punitive damages claims. The Court relied on congressional intent, as evidenced by the legislative history of the Atomic Energy Act, to "tolerate whatever tension there was" between exclusive federal regulation of nuclear safety and a state's award of compensatory and punitive damages based on its own tort law. *Id.* at 256. By contrast, the MDA contains an *express* preemption provision that clearly communicates Congress's intent to centralize regulation of medical devices with the FDA and not to tolerate a tension between state and federal requirements.

CONCLUSION

For all the reasons set forth above, this Court should rule in favor of Medtronic and find that Section 360k preempts all the Lohrs' claims.

Respectfully submitted,

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March 13, 1996

APPENDIX

CORPORATE MEMBERS OF THE PRODUCT LIABILITY ADVISORY COUNCIL

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AlliedSignal
Aluminum Co. of America
American Automobile Manufacturers Assn.
American Brands, Inc.
American Home Products Corp.
American Suzuki Motor Corp.
Andersen Corporation
Anheuser-Busch Companies
AT&T/Lucent Technologies Inc.
Atlantic Richfield Co.
Baxter International Inc.
Becton-Dickinson & Company
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Porsche Cars North America, Inc.
Premark International, Inc.
Procter & Gamble Co.
RJ Reynolds Tobacco Co.
Rockwell International Corporation
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Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
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Whirlpool Corp.
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Yamaha Motor Corp. USA

(8) (9)

Nos. 95-754, 95-886

Supreme Court, U.S.
FILED
MAR 13 1996
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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/Cross-Petitioners.

ON WRITS OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER/CROSS-RESPONDENT

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41 pp

TABLE OF CONTENTS

Page

INTERESTS OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 6

I. THE PLAIN LANGUAGE OF THE FDCA EVIDENCES CONGRESS' INTENT TO PRE-EMPT STATE LAW DAMAGES CLAIMS FOR MANUFACTURING AND DESIGN DEFECT AND FAILURE TO WARN 6

A. The Plain Language of the Statute Governs Whether State Law is Pre-Empted Absent Clearly Expressed Congressional Intent Not to Pre-Empt State Law. 6

B. Section 360k(a) Sets Forth a Four-Part Test for Pre-Emption 8

C. Section 360j(a) Identifies the Federal "Requirements" Triggering Pre-Emption Under § 360k(a) as Including the FDCA's Requirements Regarding Adulterated And Misbranded Medical Devices, Labeling, Good Manufacturing Practices, Registration of Medical Devices, Record-Keeping, and Reporting . . 10

D. The Requirements Listed in § 360j(a) Are Comprehensive to Ensure the Safety and Effectiveness of All Medical Devices . 12

1. Regulation of Devices Before Enactment of the MDA 12

2. The MDA Regulatory Scheme 13

a. Section 351 -- FDCA Requirements to Prevent the Marketing of Adulterated Devices 13

b. Section 352 -- FDCA Requirements to Prevent the Marketing of Misbranded Devices 15

c. Section 360 -- Device and Manufacturer Registration Requirements; Authorization of § 510(k) Clearance 16

d. Section 360i -- Record-Keeping and Reporting Requirements 17

e. Sections 360c, 360d, 360e, and 360j(g) -- Device Classification, Performance Standards, Premarket Approval, and Investigational Devices 18

3. The FDA Has Comprehensive Powers to Enforce These Requirements 19

E. Claims Alleging Design or Manufacturing Defect or Failure to Warn Are Necessarily "Different From, or in Addition to" These Federal "Requirements" 20

II. THE ELEVENTH CIRCUIT ERRED IN DEFERRING TO THE FDA'S INTERPRETATION OF § 360k(a) BECAUSE THAT INTERPRETATION REWRITES § 360k(a) AND IS INCONSISTENT WITH OTHER PROVISIONS OF THE FDCA AND CONGRESS' INTENT TO PRE-EMPT . 24

A. No Deference Is Due to an Agency Interpretation That Conflicts with the Plain Meaning of a Statute 24

B. The Eleventh Circuit's Reliance On FDA Regulation § 808.1(d) 25

C. 21 C.F.R. § 808.1(d) Conflicts with the Plain Meaning of the FDCA and Thwarts Congressional Intent 27

1. 21 C.F.R. § 808.1(d) is Inconsistent with the FDCA's Definition of the Federal "Requirement." 27

2. 21 C.F.R. § 808.1(d) Undermines Congressional Intent by Subjecting Medical Devices to Overburdensome Regulation and to Lay Determinations of Safety And Effectiveness 29

CONCLUSION 30

TABLE OF AUTHORITIES

Cases: **Page**

Board of Governors, FRS v. Dimension Fin. Corp., 474 U.S. 361 (1986) 24
Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 838 (1984) . . 24, 25
Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 4, 8
Consumer Product Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102 (1980) 8
CSX Transp., Inc. v. Easterwood, 507 U.S. 658 (1993) 6, 7
Demarest v. Manspeaker, 498 U.S. 184 (1991) 24
Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469 (1992) 11, 24
FMC Corp. v. Holliday, 498 U.S. 52 (1990) 7
Hillsborough County v. Automated Medical Lab., Inc., 471 U.S. 707 (1985) 25
INS v. Cardoza-Fonseca, 480 U.S. 421 (1987) 7, 25
John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank, 114 S. Ct. 517 (1993) 24
Jones v. Rath Packing Co., 430 U.S. 519 (1977) 7
Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) 26
Mackey v. Lanier Collection Agency & Serv., 486 U.S. 825 (1988) 29

Page

Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995) 25
Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989) 28
Morales v. Trans World Airlines, Inc., 504 U.S. 374 (1992) 7
National R.R. Passenger Corp. v. Boston & Maine Corp., 503 U.S. 407 (1992) 24
Park N' Fly, Inc. v. Dollar Park and Fly, Inc., 469 U.S. 189 (1985) 8
Public Employees Retirement Sys. of Ohio v. Betts, 492 U.S. 158 (1989) 24
Russello v. United States, 464 U.S. 16 (1983) 29
Shaw v. Delta Airlines, Inc., 463 U.S. 85 (1983) 7
Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) 7
Sorenson v. Secretary of Treasury, 475 U.S. 851 (1986) 11

Statutes:

Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-395 (1994) . . . . . *passim*

21 U.S.C. § 331 13
21 U.S.C. § 332 20
21 U.S.C. § 333 20
21 U.S.C. § 333(g)(1)(A) 20
21 U.S.C. § 334(a)(2)(D) 20

Page

21 U.S.C. § 334(g) 20
21 U.S.C. § 351 . . . . . 2-4, 10-13, 15, 18-20, 28
21 U.S.C. § 351(a) 14
21 U.S.C. § 351(e) 14
21 U.S.C. § 351(f) 14
21 U.S.C. § 351(g) 14
21 U.S.C. § 351(h) 13
21 U.S.C. § 351(i) 14
21 U.S.C. § 352 . . . . . 2-4, 10, 11, 15, 16, 18-20, 28
21 U.S.C. § 352(a) 15, 20
21 U.S.C. § 352(b) 16
21 U.S.C. § 352(c) 16
21 U.S.C. § 352(e)(2) 16
21 U.S.C. § 352(f) 13, 15
21 U.S.C. § 352(f)(1) 20
21 U.S.C. § 352(j) 15, 20
21 U.S.C. § 352(o) 16
21 U.S.C. § 352(p) 16
21 U.S.C. § 352(q) 16
21 U.S.C. § 352(r) 16
21 U.S.C. § 352(s) 16
21 U.S.C. § 352(t) 15
21 U.S.C. § 360 . . . . . 2-4, 10-12, 16-19, 28
21 U.S.C. § 360(b) 16
21 U.S.C. § 360(c) 16
21 U.S.C. § 360(h) 17
21 U.S.C. § 360(j)(1) 16
21 U.S.C. § 360(j)(2)(A) 17
21 U.S.C. § 360(k) (§ 510(k) of FDCA) . . . . . *passim*
21 U.S.C. § 360c 18, 19
21 U.S.C. § 360c(a)(1)(A) 19
21 U.S.C. § 360c(a)(1)(B) 19
21 U.S.C. § 360c(c)(3) 19

Page

21 U.S.C. § 360d 2, 4, 10-12, 18, 19
21 U.S.C. § 360e 2, 4, 10-12, 18-20
21 U.S.C. § 360f 20
21 U.S.C. § 360h 15
21 U.S.C. § 360h(a) 15
21 U.S.C. § 360h(e)(1) 20
21 U.S.C. § 360i 2-4, 10-12, 17-20, 28
21 U.S.C. § 360i(a) 17
21 U.S.C. § 360i(b) 17
21 U.S.C. § 360i(f)(1)(A) 17
21 U.S.C. § 360j 15
21 U.S.C. § 360j(a) 2-6, 10-13, 18, 23
21 U.S.C. § 360j(f) 11
21 U.S.C. § 360j(f)(1) 13
21 U.S.C. § 360j(g) 2, 4, 10-12, 18-20
21 U.S.C. § 360k(a) 1-6, 8-11, 23-29
21 U.S.C. § 360k(a)(1) 26
21 U.S.C. § 360k(b) 9
21 U.S.C. § 360*l* 15
21 U.S.C. § 360*l*(a) 16
21 U.S.C. § 360ss 6, 28, 29
21 U.S.C. § 373 13
21 U.S.C. § 374 13
21 U.S.C. § 374(a)(1) 17

Regulations:

21 C.F.R. Part 820 13

21 C.F.R. § 801.109(c) 15
21 C.F.R. § 803.31(d) 17

	Page
21 C.F.R. § 808.1(d)	5, 25, 27-28
21 C.F.R. § 808.1(d)(1)	27
21 C.F.R. § 812.140	17
21 C.F.R. § 812.5	15
21 C.F.R. § 820.100(a)(2)	14
21 C.F.R. § 820.121	15
21 C.F.R. § 820.162	14
21 C.F.R. § 820.180	17
21 C.F.R. § 820.198	14
21 C.F.R. § 820.20(a)(3)	14
21 C.F.R. § 820.5	14

Miscellaneous:

53 Fed. Reg. 8854 (1978)	14
Guido Calabresi, *The Costs of Accidents* (1970)	22
H. Rep. No. 853, 94th Cong., 2d Sess. (1976)	29

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation ("WLF") is a non-profit public interest law and policy center with more than 100,000 supporters nationwide. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise principles, and a limited and accountable government. To that end, WLF has appeared before this and other federal and state courts in cases involving federal pre-emption issues, arguing that the American economy suffers when multiple layers of government seek simultaneously to regulate the same business activity. WLF appears here by written consent of the parties, on file with the Clerk of the Court.

Medtronic's and the Lohrs' briefs collectively ask whether § 521(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k(a) (1994), pre-empts state law damages claims for manufacturing defect, design defect, and failure to warn with respect to a medical device -- here a pacemaker lead -- that obtained United States Food and Drug Administration ("FDA") clearance for marketing under § 510(k) of the FDCA.[1/] Section 510(k), and the regulations promulgated thereunder, provide one pathway, among several, for a medical device to be cleared for marketing. WLF agrees with Medtronic that FDCA § 510(k) imposes "requirements" meriting pre-emption of the Lohrs' state common law claims.

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1 Because this premarket clearance process is commonly referred to by its section number in the FDCA, WLF retains the § 510(k) nomenclature instead of citing the corresponding section in the United States Code (21 U.S.C. § 360(k) (1994)).

Pre-emption under § 360k(a)[2], however, should not turn on how a medical device enters the market, but rather on the unambiguous language of the immediately preceding section -- § 360j(a) -- which identifies pre-emptive "requirement[s] applicable under the [the FDCA]" as the requirements authorized or established by § 351 (relating to adulterated devices and authorizing the FDA's good manufacturing regulations), § 352 (relating to misbranded devices), § 360 (relating to the registration of devices and including authorization of the 510(k) process), and § 360i (relating to records and reports on devices), *and* any additional "requirements" imposed on a medical device by the FDA at its discretion under § 360d (relating to performance standards), § 360e (relating to premarket approval), and § 360j(g) (relating to exemptions for investigational use devices). 21 U.S.C. § 360j(a) (1994).[3] Under the express language of the FDCA -- which must control the issue of pre-emption -- if any of these requirements is applicable to the device, that requirement pre-empts state common law damages claims for manufacturing defect, design defect, and failure to warn.

SUMMARY OF ARGUMENT

When a statute contains an express pre-emption clause, like § 360k(a), the plain meaning of that clause, considered in light of its statutory context, is the best evidence of Congress' pre-emptive intent. For pre-emption to occur under § 360k(a), four criteria must be satisfied: (1) a state

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2 Unless otherwise stated, a reference to a "section" or "§" is to a section of Title 21 of the United States Code, 1994 Edition.

3 Section 360j(a) is reprinted in the attached Appendix.

"requirement" that (2) "is different from, or in addition to" (3) a federal "requirement" under the FDCA, and that (4) "relates to" the "safety or effectiveness" of the device or to any other matter included in a "requirement applicable" to the device under the FDCA. We provide this Court with a statutory basis for defining a federal "requirement" under the third criterion, and show that these federal requirements pre-empt all of the Lohrs' claims.

Section 360j(a) is the key to defining the federal "requirement applicable to a device" in § 360k(a). Section 360j(a) employs language *identical* to the federal "requirement" in § 360k(a), and expressly identifies those requirements as the FDCA's comprehensive general controls regarding:

- Adulterated devices, including authorization of the FDA's good manufacturing practices regulations (§ 351);

- Misbranded devices, including requirements regarding false or misleading labeling or inadequate warnings (§ 352);

- Registration of manufacturers and their devices, which enables the FDA to evaluate compliance with its safety and effectiveness requirements and authorizes the 510(k) clearance process (§ 360); and

- Continuous evaluation of medical devices by extensive requirements as to the recording and reporting of, among other things, "adverse device experiences" (§ 360i).

Section 360j(a) further identifies FDA discretionary action capable of imposing additional "requirements" under the following FDCA provisions: § 360d (relating to performance standards), § 360e (relating to premarket approval), and § 360j(g) (relating to exemptions for investigational use devices).[4/]

Under well-established principles of statutory construction, the phrase "requirement applicable to a device" should be given the same meaning wherever it appears in the statute. Thus, the comprehensive FDCA requirements identified in § 360j(a) are plainly the "requirement[s] applicable under this chapter to the device" referred to in § 360k(a). While the 510(k) clearance process is but one of these requirements, it is the applicability of "any" of the FDCA requirements identified in § 360j(a) -- i.e., §§ 351, 352, 360, or 360i -- that triggers pre-emption under § 360k(a). These "requirements" collectively create a regulatory web designed to ensure that medical devices are safe and effective; this regulatory web captures all aspects of the manufacture and design of medical devices and disclosures and warnings

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4 Section 360j(a)'s definition of "requirement applicable to a device under this chapter" does not delimit the definition of a State requirement "with respect to a device" to statutory and regulatory requirements. Section 360j(a) only refers to statutory and regulatory requirements because those are the only kinds of requirements created by the FDCA, not because those are the only way "requirements" can be created. Not bound by the FDCA, a State can create a requirement by statute, regulation, or common law. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion) (common law claims create requirements); *id.*, 505 U.S. at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part).

regarding proper and effective use of these devices. Accordingly, a state court judgment finding a manufacturing defect, design defect, or failure to warn is necessarily "different from, or in addition to" the requirements that spin this regulatory web. Because of the comprehensiveness of these requirements, it was reasonable for Congress to incorporate them as the federal requirements that pre-empt all state common law claims for manufacturing defect, design defect, and failure to warn with respect to a medical device subject to the FDCA.

The Eleventh Circuit below invoked an FDA regulation, 21 C.F.R. § 808.1(d) (1995), to narrow Congress' express choice of words in the FDCA. An administrative agency, however, cannot rewrite a statute under the guise of interpreting it. When it does so -- as the FDA did in promulgating 21 C.F.R. § 808.1(d) -- the agency's interpretation is not entitled to any deference, and the Eleventh Circuit's ruling to the contrary is erroneous.

As noted above, the FDCA sets forth extensive federal requirements to prevent the adulteration or misbranding of medical devices, to ensure the proper manufacture, design, and labeling of medical devices, to require registration of medical devices, and to require the reporting of any adverse information about such devices. In 21 C.F.R. § 808.1(d), the FDA blunts the force of Congress' broad statement of pre-emption in § 360k(a) by ignoring § 360j(a)'s identification of these "applicable" federal "requirements," and providing instead that state requirements are pre-empted *only* when the "FDA has established" *specific counterpart* regulations or there are other *specific* requirements applicable to a particular device under the act. The FDA has thus re-written § 360k(a) by adding the modifiers "specific," "particular," and

"counterpart," when no such limiting terms appear in § 360k(a) or § 360j(a).

To the extent they exclude general controls as pre-emptive federal "requirements," these modifiers are inconsistent with the express language of the FDCA, which defines "requirements" to include the requirements identified in § 360j(a). They are also inconsistent with § 360k(a) when read in the context of another FDCA pre-emption provision in which Congress itself chose to use narrowing language to limit the scope of pre-emption. *See* 21 U.S.C. § 360ss (provision providing narrower pre-emption for electronic products subject to the FDCA). Finally, the FDA's redraft of § 360k(a) contravenes the undisputed purpose of the MDA, which added § 360k(a) to the FDCA precisely to encourage innovation by reducing the burden of over-regulation while assuring the public that medical devices will be safe and effective.

ARGUMENT

I. THE PLAIN LANGUAGE OF THE FDCA EVIDENCES CONGRESS' INTENT TO PRE-EMPT STATE LAW DAMAGES CLAIMS FOR MANUFACTURING AND DESIGN DEFECT AND FAILURE TO WARN.

A. The Plain Language of the Statute Governs Whether State Law is Pre-Empted Absent Clearly Expressed Congressional Intent Not to Pre-Empt State Law.

Under the Supremacy Clause of the United States Constitution, state law that conflicts with or frustrates the objectives of a federal statute is pre-empted. *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, ____, 113 S. Ct. 1732, 1737 (1993). Whether a federal statute pre-empts state law depends on congressional intent. *FMC Corp. v. Holliday*, 498 U.S. 52, 56 (1990). "Pre-emption may be either express or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Id.* at 56-57 (internal quotation marks omitted). "Evidence of pre-emptive purpose is sought in the text and structure of the statute at issue." *CSX*, 113 S. Ct. at 1737.

If the statute contains an express pre-emption clause, then the task of assessing congressional intent must start with "the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id.*; *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992). If the clause standing alone is not clear, then congressional intent is determined by ascertaining the meaning of the clause from the text and structure of the statutory scheme in which the clause appears. *See, e.g., Morales*, 504 U.S. at 385-86; *Shaw v. Delta Airlines, Inc.*, 463 U.S. 85, 98 (1983); *Jones v. Rath Packing Co.*, 430 U.S. 519, 532 (1977). When the plain language of the statute as a whole appears to settle the question, the Court looks to legislative history *solely* to determine "whether there is 'clearly expressed legislative intention contrary' to that language, which would require us to question the strong presumption that Congress expresses its intent through the language it chooses." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 432 n.12 (1987).

While this Court has expressed on occasion its reluctance to pre-empt common law damages claims,[5/] it has also recognized that any such hesitation must give way to the language Congress chose to express its intent to pre-empt. Thus "[a]bsent clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Consumer Product Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992); *Park N' Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189, 194 (1985).

B. Section 360k(a) Sets Forth a Four-Part Test for Pre-Emption.

Section 360k(a) provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

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5 *E.g.*, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

21 U.S.C. § 360k(a).[6/] Thus, to establish pre-emption under § 360k(a), one must demonstrate:

- a state "requirement";
- a federal "requirement applicable . . . to the device" under the FDCA;
- that the state "requirement" is "different from, or in addition to" the federal "requirement applicable . . . to the device" under the FDCA; and
- that the state "requirement" "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the FDCA.

This *amicus* brief addresses the FDCA's identification of the federal requirements that pre-empt state common law claims for manufacturing and design defect and failure to warn.

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6 Section 360k(b) authorizes the FDA to grant exemptions from pre-emption under § 360k(a). No such exemption is applicable here.

C. Section 360j(a) Identifies the Federal "Requirements" Triggering Pre-Emption Under § 360k(a) as Including the FDCA's Requirements Regarding Adulterated and Misbranded Medical Devices, Labeling, Good Manufacturing Practices, Registration of Medical Devices, Record-Keeping, and Reporting.

The FDCA, as amended by the MDA, applies requirements to *all* medical devices independently from the process by which such devices reach the market, and those requirements include the general controls "requirements" identified in § 360j(a) of the FDCA. As noted above, § 360k(a) pre-empts a state requirement with respect to a device "*intended for human use,*" which is different from, or in addition to, "*any requirement applicable under this chapter to the device . . . .*" In the immediately preceding section of the FDCA -- § 360j(a) -- Congress provided that:

> *Any requirement* authorized by or under section 351, 352, 360, or 360i of this title *applicable to a device intended for human use* shall apply to such device until the *applicability of the requirement to the device* has been changed by action taken under section 360c, 360d, or 360e of this title or under subsection (g) of this section, and any *requirement* established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a *requirement* imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

21 U.S.C. § 360j(a) (emphasis added).

Congress thus employed in § 360j(a) language identical to the language it used in expressing the federal requirement for pre-emption in § 360k(a) -- "any requirement . . . applicable to a device." In referring to "[a]ny requirement . . . applicable to a device" in § 360j(a), Congress expressly incorporated the "requirements" authorized or established by § 351 (adulterated devices, which incorporates the good manufacturing practices regulations), § 352 (misbranded devices, which provides the vehicle for all labeling requirements), § 360 (registration of devices, including authorization of § 510(k) clearance), and § 360i (record-keeping and reporting). Congress further provided for additional "requirements" that may be imposed by FDA action taken under § 360d (performance standards), § 360e (premarket approval), and § 360j(g) (investigational device exemption).

Because § 360k(a) employs the identical phrase "any requirement applicable to a device," that language necessarily must also incorporate the requirements of §§ 351, 352, 360, and 360i and any additions to these requirements imposed by discretionary FDA action under §§ 360d, 360e, or 360j(f). *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992) (citing the "basic canon of statutory construction that identical terms within an Act bear the same meaning" and rejecting agency interpretation inconsistent with that meaning); *Sorenson v. Secretary of Treasury*, 475 U.S. 851, 860 (1986) ("The normal rule of statutory construction assumes that identical words used in different parts of the same act are intended to have the same meaning.") (internal quotation marks omitted).

While the FDA's clearance processes under § 510(k) (premarket notification), § 360j(g) (investigational device exemption), and § 360e (premarket approval) are sources

of "requirements" for pre-emption under § 360k(a), it is the applicability of the requirements established by and under §§ 351, 352, 360, and 360i, as they may be supplemented by discretionary FDA action under §§ 360d, 360e, and 360j(g), that *triggers* pre-emption under § 360k(a).[7/] As we show below, these "requirements" create a regulatory web capturing all aspects of the manufacture and design of medical devices, and labeling and warnings regarding their safe and effective usage.

D. The Requirements Listed in § 360j(a) Are Comprehensive to Ensure the Safety and Effectiveness of All Medical Devices.

1. Regulation of Devices Before Enactment of the MDA

Contrary to the Eleventh Circuit's assertion that medical devices were "largely unregulated" before 1976 (Pet. App. 2a), the FDA, in fact, regulated the activities of device manufacturers under the FDCA of 1938. The FDCA of 1938 prohibited the sale of adulterated or misbranded devices, required adequate warnings on device labels, required device manufacturers to permit FDA access to device shipping records, and authorized the FDA to enter and inspect device manufacturing facilities. Federal Food, Drug, and Cosmetic Act, ch. 675, §§ 301, 502, 703,

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7 Section 360j(a) does authorize "changes" to these requirements under sections 360c, 360d, 360e, or 360j(g), but so long as a medical device is subject to "any" of these requirements, a state requirement different from or in addition to these federal requirements is pre-empted.

704, 52 Stat. 1040, at 1042, 1050, 1057 (1938) (codified as amended at 21 U.S.C. §§ 331, 352(f), 373, 374).

2. The MDA Regulatory Scheme

The MDA substantially expanded FDA regulatory power over medical devices by providing for general controls -- the requirements identified in § 360j(a) -- applicable to all medical devices. These provisions of the FDCA set forth a regulatory scheme for all aspects of the manufacture and design of medical devices, and labeling and warnings regarding their proper and safe usage. These requirements, moreover, give the FDA comprehensive oversight once a product enters the market, and the power to remove unsafe, mislabeled, or defective devices from commerce. An examination of that scheme makes it clear why state tort judgments for manufacture or design defect, or failure to warn are necessarily "different from, or in addition to" these federal requirements, and therefore pre-empted.

a. Section 351 -- FDCA Requirements To Prevent The Marketing Of Adulterated Devices

Section 351 imposes requirements by deeming "adulterated" a device that is manufactured or designed defectively. For example, under § 351(h), a device is deemed adulterated if it was not manufactured in conformity with "applicable requirements" of the FDCA's good manufacturing practices provision, § 360j(f)(1). Under the authority of §§ 351(h) and 360j(f)(1), the FDA has promulgated "good manufacturing practices" regulations which are intended to ensure that all devices are manufactured in accordance with generally recognized principles that will result in a device that (1) functions as intended, (2) is safe

and effective, and (3) is in compliance with the FDCA.[8/] Unless the FDA grants an exemption, the GMP regulations require all medical device manufacturers to implement and monitor a comprehensive quality assurance program appropriate to the specific devices they manufacture. 21 C.F.R. § 820.5. The GMP regulations further require that as part of a quality assurance program, manufacturers identify and correct manufacturing and design defects.[9/] In addition, the GMP regulations require manufacturers to investigate complaints about a device (21 C.F.R. § 820.198), to investigate any failure of a device or any of its components to meet performance specifications after the device has been released for distribution (21 C.F.R. § 820.162), and to test each and every change made in the design and manufacture of a device (21 C.F.R. § 820.100(a)(2)).

A device is also deemed adulterated if: (1) it was manufactured under unsanitary conditions; (2) its container is composed of a dangerous substance; (3) it contains an unsafe color additive; (4) it does not comport with an applicable performance standard; (5) it does not comply with an applicable premarket approval requirement; or (6) if a manufacturer fails to comply with a "requirement" for investigational devices. 21 U.S.C. § 351(a), (e)-(g), (i).

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8 On July 18, 1978, FDA issued its Good Manufacturing Practice ("GMP") regulations, 21 C.F.R. Part 820, which became effective on December 18, 1978. 53 Fed. Reg. 8854 (1978).

9 21 C.F.R. § 820.20(a)(3).

b. Section 352 -- FDCA Requirements To Prevent the Marketing Of Misbranded Devices

To ensure that the public is properly instructed and warned as to the safe and effective use of a medical device, § 352 imposes requirements deeming devices "misbranded" under a wide array of circumstances. For example, § 352 deems a device to be misbranded if its labeling is false or misleading or lacks adequate directions for use and warnings against unsafe use. 21 U.S.C. § 352(a), (f). Additionally, a device is "misbranded" if it is dangerous to health when used in the manner recommended or prescribed in its labeling. 21 U.S.C. § 352(j).[10/]

Under § 352(t), a device is "misbranded" if there has been a failure to comply with a "requirement" prescribed in § 360h, which authorizes the FDA to take certain actions when it determines that a device presents "an unreasonable risk of substantial harm to the public health." 21 U.S.C. § 360h(a). Section 360h requires manufacturers to warn health professionals about the risks posed by such devices. *Id.* Furthermore, under § 352(t), a device is deemed "misbranded" if there is a failure to comply with a "requirement" under § 360*l*, requiring post-market surveillance of all devices first marketed after January 1, 1991, and for devices first marketed earlier if the FDA determines that

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10 Under the authority of §§ 351, 352, and 360j, the FDA has promulgated extensive regulatory requirements to ensure appropriate labeling of and warnings about all devices. *See, e.g.*, 21 C.F.R. §§ 801.109(c) (labeling of prescription devices to disclose "any relevant hazardous, contraindications, side effects, and precautions"), 812.5 (investigational devices labeling), and 820.121 (critical devices labeling).

postmarket surveillance of such a device is "necessary to protect the public health." 21 U.S.C. § 360*l*(a).

In addition to the above requirements, § 352 deems a device misbranded if (1) the label does not contain the name and address of the manufacturer, packer, or distributor, and an accurate statement of the quantity or contents; (2) the required information is not placed prominently enough on the label; (3) the established name of the device does not appear in type at least half as large as the proprietary name used; (4) it is manufactured by an unregistered establishment or not listed by a registered establishment; (5) it is a restricted device and its advertisements are false or misleading, or it is not sold or distributed in compliance with the regulations; or (6) it does not comply was an applicable performance standard labeling requirement. 21 U.S.C. § 352(b), (c), (e)(2), (o) - (s).

c. Section 360 -- Device and Manufacturer Registration Requirements; Authorization of § 510(k) Clearance

To aid the FDA in enforcing the FDCA's requirements regarding the manufacture, design, and labeling of devices, § 360 requires all persons who engage in "the manufacture, preparation, propagation, compounding, or processing of a . . . device" to register their establishments with the FDA. 21 U.S.C. § 360(c). Each such establishment is required to re-register annually. 21 U.S.C. § 360(b). To alert the FDA to the existence of devices requiring its regulatory oversight, each person initially registering an establishment with the FDA must also provide a list of all devices manufactured or distributed by the establishment, and must update that list to include devices that are subsequently manufactured or distributed. 21 U.S.C. § 360(j)(1),

(j)(2)(A). Section 360, moreover, subjects every registered establishment to inspection for the express "purposes of enforcement" of the FDCA. 21 U.S.C. §§ 360(h), 374(a)(1).[11/]

d. Section 360i -- Record-Keeping And Reporting Requirements

Section 360i imposes substantial record-keeping and reporting requirements in an effort, among other things, to alert the FDA to adverse information about a device and to allow the manufacturer to correct the device's design, or in the worst case, to enable the FDA to ban the device altogether. Thus, it requires manufacturers to keep records of, and submit reports to the FDA concerning, deaths or serious injuries that may have been caused by a device, as well as any dangerous malfunctions. 21 U.S.C. § 360i(a). Health care facilities, moreover, are required to report to the FDA and the manufacturer "information that reasonably suggests that a device has or may have caused or contributed to the death" or "serious illness" of a patient. 21 U.S.C. § 360i(b).[12/] To prevent defectively designed or manufactured devices from remaining on the market, § 360i(f)(1)(A) requires manufacturers to report removals

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11 Included within § 360 is § 360(k) (§ 510(k) of the FDCA), the pathway to the market for Medtronic's pacemaker lead. The requirement of a 510(k) submission is only one of the many FDCA "requirements" that became applicable to the pacemaker lead from the moment the MDA was enacted.

12 Under the authority of § 360i, the FDA has promulgated extensive medical device record-keeping and reporting requirements. *See, e.g.*, 21 C.F.R. §§ 820.180, 803.31(d), 812.140.

of devices undertaken to reduce health risks posed by the device.

e. Sections 360c, 360d, 360e, And 360j(g) -- Device Classification, Performance Standards, Premarket Approval, And Investigational Devices

Under § 360j(a), the FDA has authority to take action under § 360c (classification of devices), 360d (performance standards), § 360e (premarket approval), and § 360j(g) (exemption for investigational devices[13]) that can change, or make inapplicable, requirements imposed by or under §§ 351, 352, 360, and 360i. As noted earlier, § 360j(a) further vests power in the FDA under §§ 360d, 360e, and 360j(g) to establish device-specific rules that *add* requirements to the general controls in §§ 351, 352, 360, and 360i.

With the enactment of the MDA, all devices became subject to the general controls set forth in §§ 351, 352, 360, and 360i. For purposes of determining whether devices should continue to be subject to the requirements of these general controls, or whether additional requirements should be imposed through the requirements of performance standards or premarket approval, the MDA required the FDA to convene expert panels to classify every medical device, including pre-amendment devices already regulated by the FDA under the FDCA of 1938. Indeed, pre-amendment devices were to be classified within one year

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13 Investigational use devices are experimental devices that are of such medical importance and immediacy to the sick as to require expedited approval and monitoring procedures under the close supervision of medical experts.

after the MDA was funded. 21 U.S.C. § 360c(c)(3).

Section 360c thus requires the FDA to classify all devices into one of three classes, with Class I consisting of devices for which general controls are "sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A). Class II is home to those devices for which general controls are not sufficient to provide reasonable assurance of the safety and effectiveness of the device, but for which sufficient information exists to establish special controls to provide such assurance. 21 U.S.C. § 360c(a)(1)(B). Such special controls include "performance standards" promulgated pursuant to § 360d -- one of the provisions under which the FDA can impose a supplemental requirement applicable to a device.

Class III, providing for premarket approval, is reserved for devices requiring the greatest scrutiny because neither general controls regulations nor special controls are sufficient to provide reasonable assurance of safety and effectiveness. Section 360e thus supplements the requirements in the general controls of §§ 351, 352, 360, and 360i by requiring premarket approval for devices that the FDA has determined merit the highest level of controls. This does not alter the fact that it is "applicability" of the requirements of the general controls in §§ 351, 352. 360, and 360i -- and not any premarket review process -- that triggers pre-emption of state common law claims for manufacturing and design defect and failure to warn.

3. The FDA Has Comprehensive Powers to Enforce These Requirements.

The FDA has broad enforcement powers against de-

vices that it believes do not comply with §§ 351 and 352. It can detain adulterated or misbranded devices without prior notice to the manufacturer, or seek the seizure and forfeiture of adulterated or misbranded devices. 21 U.S.C. §§ 334(g), 334(a)(2)(D). It can seek an injunction against prohibited conduct or against continued manufacture or distribution of a device that does not comply with §§ 351, 352, 360, 360i, 360e, or 360j(g). 21 U.S.C. § 332.

The FDA can seek felony or misdemeanor criminal prosecution of individuals or corporations for the marketing of adulterated or misbranded devices under §§ 351 and 352. 21 U.S.C. § 333. Civil fines from $15,000 to $1,000,000 for violating a "requirement of this chapter" may also be assessed. 21 U.S.C. § 333(g)(1)(A). The FDA can, among other remedies, also require changes in the labeling of a device (21 U.S.C. § 352(a), (f)(1), (j)), recall a device (21 U.S.C. § 360h(e)(1)), or ban the device altogether (21 U.S.C. § 360f).

E. Claims Alleging Design or Manufacturing Defect or Failure to Warn Are Necessarily "Different From, Or In Addition To" These Federal "Requirements."

The purpose of these comprehensive federal requirements is to ensure that only safe and effective products enter commerce. The requirements are also intended to ferret out unsafe or defective devices already in commerce, in much the same way tort claims cause defective products to be removed from the market.

The first step in ensuring that a product is safe and effective is to require that it be designed properly. To accomplish this, the FDCA first requires that all registered

manufacturers "list" all devices they market. The FDA then begins regulating the design of a listed device, from classifying devices (in order to determine whether, or which, special controls should be applied) down to regulating even what color additives "adulterate" a device. If the FDA determines that general FDCA requirements are not sufficient to ensure the safety and efficacy of a device, the FDA may require that a device satisfy rigorous premarket approval requirements or any other "requirement" it deems necessary.

The FDA must also approve any change in the design of a device that could affect its safety or efficacy. A jury verdict finding a design defect is necessarily a determination that a device's design should be changed to make the device safe and effective. Without pre-emption, whether the design of a medical device should be changed would be within the jury's province, thus supplanting the FDA's approval and supervision of all changes in the design of medical devices that could affect their safety or efficacy.

If, despite these requirements, a defectively designed device enters commerce, the federal requirements outlined above provide systematic opportunities -- in contrast to case-by-case determinations of lay juries -- for identifying those devices and removing them from commerce, if necessary. For example, manufacturers and hospitals must report adverse information about a device, and the FDA has broad inspection powers, including of manufacturer records of adverse information. In addition, all devices are subject to post-market surveillance by the FDA itself to identify unsafe or defective devices.

When faced with a defective device, the FDA can require corrective action, recall the device, or require its

replacement with a properly designed device. The civil and criminal penalties set forth above also give manufacturers strong incentives to design safe devices. Jury verdicts in products liability cases also create incentives for manufacturers -- indeed, this is the *raison d'etre* for imposing liability under a strict liability in tort theory[14/] -- but in a far less comprehensive way than do the requirements administered by the FDA.

Using these same requirements, the FDCA ensures that products will be manufactured safely and effectively. Witness the FDCA's specification of detailed good manufacturing practices, its requirement that all manufacturing establishments register with the FDA, and the FDA's extensive right to inspect every registered manufacturing establishment for, among other things, compliance with these and other manufacturing requirements. Any noncomplying device is deemed "adulterated" and is subject to being seized or recalled. Through the FDCA's comprehensive record-keeping and reporting requirements, defectively manufactured devices are subject to the same continuous review and evaluation by manufacturers, health care professionals, and the FDA as are defectively designed devices. And the FDA's remedies when presented with a defectively manufactured device are equally broad and create the same incentives to manufacturers to produce -- as well as design -- safe and effective devices.

The FDCA contains a panoply of requirements regarding the labeling of devices to ensure that the labeling contains adequate instructions as to a device's proper use and warnings as to its unsafe use. Again, these requirements range from regulating adequate warnings against unsafe use down to specifying every detail of the label's appearance. Indeed, a device is mislabeled (or "misbranded" in the FDCA's parlance) -- and therefore subject to being, among other things, recalled or seized -- if the device is dangerous even when used as recommended (*i.e.*, defectively designed).

The MDA also requires that the FDA convene expert panels to classify every medical device to determine whether the nature of a device merits requirements additional to those in the general controls identified in § 360j(a). A jury verdict finding a manufacturing or design defect or the failure to warn thus displaces the FDA and its expert panel's recommendation as to the level of requirements appropriate for the device at issue.

Given these all-encompassing requirements of the FDCA, a jury verdict finding a design or manufacturing defect, or a failure to warn is necessarily "different from, or in addition to," these federal requirements. Given the comprehensiveness of these "requirements" and the incentives they give manufacturers to design and manufacture safe and effective devices and provide adequate instructions as to safe usage, it was reasonable for Congress, in § 360k(a), to pre-empt state common law claims for design defect, manufacturing defect, and failure to warn.

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14 *See* Guido Calabresi, *The Costs of Accidents* 133-38 (1970).

II. THE ELEVENTH CIRCUIT ERRED IN DEFERRING TO THE FDA'S INTERPRETATION OF § 360k(a) BECAUSE THAT INTERPRETATION REWRITES § 360k(a) AND IS INCONSISTENT WITH OTHER PROVISIONS OF THE FDCA AND CONGRESS' INTENT TO PRE-EMPT.

A. No Deference Is Due to an Agency Interpretation That Conflicts with the Plain Meaning of a Statute.

Reasonable interpretations by an agency of a statute that it administers are entitled to deference from the judiciary if the text of the statute is ambiguous. *National R.R. Passenger Corp. v Boston & Maine Corp.*, 503 U.S. 407, 417 (1992); *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 838, 843 (1984). This deference, however, must not be applied to alter the clearly expressed intent of Congress. *Board of Governors, FRS v. Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986); *Chevron*, 467 U.S. at 843 n.9 ("The judiciary . . . must reject administrative constructions which are contrary to clear congressional intent."). Courts have an obligation to "give effect to the clear meaning of statutes as written." *Estate of Cowart*, 505 U.S. at 476. No deference, therefore, is due to agency interpretations that conflict with the plain language of a statute. *John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 114 S. Ct. 517, 531 (1993); *Demarest v. Manspeaker*, 498 U.S. 184, 190, (1991); *Public Employees Retirement Sys. of Ohio v. Betts*, 492 U.S. 158, 171, (1989).[15] "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43; *Cardoza-Fonseca*, 480 U.S. at 446-48.

B. The Eleventh Circuit's Reliance On FDA Regulation § 808.1(d)

21 C.F.R. § 808.1(d) purports to interpret § 360k(a) by providing, in pertinent part, that:

> State or local requirements are pre-empted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . .

21 C.F.R. § 808.1(d) (1995). Some courts have interpreted this regulation not to conflict with the MDA's pre-emption provision. For example, the Third Circuit has held that even though general control requirements, such as labeling requirements and good manufacturing practices, are "generally applicable regulations," they still "present 'specific requirements applicable to a particular device under the act'" giving rise to pre-emption. *Michael v.*

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15 *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707 (1985), is inapposite because it involved implied pre-emption, not express pre-emption, and deference to the FDA's interpretation of its own regulations, not to the FDA's interpretation of a statute. *See id.* at 714-15.

Shiley, Inc., 46 F.3d 1316, 1324 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995).

Other courts, pointing to the FDA's use of the words "specific" and "particular" in the regulation, have held, like the Ninth Circuit, that generally applicable FDCA requirements do not "qualif[y] as a '*specific* requirement applicable to a *particular* device.'" *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (1995) (PMA regulations do not trigger pre-emption). If the Ninth Circuit's interpretation is correct, then the FDA's regulation is in direct conflict with the statute, because it eliminates general control requirements from the scope of the phrase "requirement applicable under this chapter" in § 360k(a)(1).

In the case below, the Eleventh Circuit announced that § 360k(a) is ambiguous, and therefore deferred to the FDA's regulation.[16/] The Eleventh Circuit should not have deferred to the FDA's interpretation of the statute, because that interpretation is contrary to express and unambiguous congressional intent. In fact, 21 C.F.R. § 808.1(d) rewrites the federal and state requirement criteria of

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16 The court offered its own interpretation of the regulation, holding that the term "specific requirements" does not require that the regulation specify the device by name, but only that the regulation be "'restricted by nature' to a particular process, procedure, or device . . . ." Pet. App. 22a. Because GMP requirements are "specific to manufacturing," *id.* at 31a, and "labeling requirements constitute specific requirements for preemption purposes," *id.* at 33a, negligent manufacture and failure to warn claims are pre-empted. The court of appeals found that general control requirements do not "establish any specific design requirements," *id.* at 29a, and therefore concluded that design defect claims are not pre-empted.

§ 360k(a). Under the guise of interpretation, the FDA has added the following boldfaced terms to § 360k(a):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement **(except for a requirement of general applicability)**[17/] --
>
> (1) which is different from, or in addition to, any **specific counterpart** requirement applicable under this chapter to the **particular** device, and
>
> (2) which relates to the safety or effectiveness of the **particular** device or to any other matter included in a **specific counterpart** requirement applicable to the **particular** device under this chapter.

C. 21 C.F.R. § 808.1(d) Conflicts with the Plain Meaning of the FDCA and Thwarts Congressional Intent.

1. 21 C.F.R. § 808.1(d) is Inconsistent with the FDCA's Definition of the Federal "Requirement."

The FDA's pre-emption regulation provides that state and local requirements are pre-empted *only* when the FDA "has established specific counterpart regulations or there

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17 The Product Liability Advisory Council, Inc.'s *amicus* brief addresses the inconsistency between the statute and this interpretative gloss added by 21 C.F.R. § 808.1(d)(1).

are other specific requirements applicable to a particular device under the act . . ." 21 C.F.R. § 808.1(d).

The FDA's addition of the limiting terms "specific" and "particular" to the statute contradicts the plain meaning of § 360k(a) -- and therefore congressional intent -- because as set forth in Subsection I.C., *supra*, the federal "requirement[s] applicable under this chapter" clearly include, at a minimum, FDCA requirements authorized or established by §§ 351, 352, 360, and 360i.

The FDA's insertion of the word "counterpart" into the MDA's pre-emption provision also conflicts with the FDCA's express language. This term invites a comparison between the state and federal requirements applicable to a device to determine whether they are "counterparts." *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (5th Cir. 1989) (federal labeling requirements do not pre-empt design requirements imposed by state tort law). The regulation thus imposes a nexus requirement on pre-emption.

If, however, Congress had intended to require a nexus between state and federal requirements as a precondition for pre-emption, then it would have written the statute to require such a nexus. For example, in another pre-emption provision in the FDCA that applies to performance standards for electronic products, Congress imposed just such a nexus requirement:

> Whenever [a certain federal standard is in effect], no State or political subdivision shall have any authority either to establish, or to continue in effect, any standard which is *applicable to the same aspect of performance* of such product . . .

21 U.S.C. § 360ss (italics added). This is a much narrower form of pre-emption: state standards are pre-empted only if they apply to the same aspect of performance as the federal standard. No such limitation appears in § 360k(a), and the FDA is entitled to no deference when it inserts such limiting language into the FDCA. *See Mackey v. Lanier Collection Agency & Serv.*, 486 U.S. 825, 836-37 (1988) (Court will not "imply a limitation on a pre-emption provision in one portion of the statute that Congress made express in another portion of ERISA."); *Russello v. United States*, 464 U.S. 16, 23 (1983) ("'[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'").

2. 21 C.F.R. § 808.1(d) Undermines Congressional Intent by Subjecting Medical Devices to Overburdensome Regulation and to Lay Determinations of Safety and Effectiveness.

The FDA's effort to limit the clear scope of pre-emption under § 360k(a) through its pre-emption regulation is inconsistent with the undisputed purposes of the MDA, which are to encourage innovation by reducing the burden of overregulation, while at the same time ensuring the public that such devices will be safe and effective. H. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Under the FDA's purported "interpretation" of § 360k(a), pre-emption would be determined on a case-by-case basis and subject to the vicissitudes of a judge, or potentially a jury if 21 C.F.R. § 808.1(d) is interpreted to raise mixed questions of fact and law. One can hardly imagine more burdensome regulation or a less effective means for assuring the public that a medical device is safe and effective where safety and

effectiveness is determined by decision makers without the expertise Congress intended to apply to regulatory decisions relating to devices.

CONCLUSION

For the foregoing reasons, WLF respectfully requests that the judgment of the court of appeals be reversed in part and affirmed in part, and the case remanded with directions to affirm the judgment of the district court.

Respectfully submitted,

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Dated: March 13, 1996

APPENDIX

21 U.S.C. § 360j(a) (1994)

§ 360j. General provisions respecting control of devices intended for human use

(a) General rule. Any requirement authorized by or under section 351, 352, 360, or 360i of this title applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under 360c, 360d, or 360e of this title or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a requirement imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

Supreme Court, U.S.
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Nos. 95-754 and 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner and Cross Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents and Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

---

BRIEF OF *AMICUS CURIAE* COLLAGEN CORPORATION IN SUPPORT OF PETITIONER AND CROSS-RESPONDENT MEDTRONIC, INC.

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BPP

QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 ("MDA") preempts common law tort claims relating to a medical device whose distribution in interstate commerce has been authorized by the Food and Drug Administration pursuant to section 510(k) of the MDA following a determination that the device is substantially equivalent to one already on the market.*

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* *Amicus curiae* Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
INTEREST OF *AMICUS CURIAE*	i
INTRODUCTION AND SUMMARY OF ARGUMENT	3
ARGUMENT	4
FEDERAL REQUIREMENTS PLACED UPON MEDICAL DEVICES PURSUANT TO THE MEDICAL DEVICE AMENDMENTS OF 1976 PREEMPT STATE LAW	4
A. Requirements Imposed on Medical Devices Found to Be Safe and Effective and Approved for Marketing Pursuant to the PMA Process Have Preemptive Effect	4
1. The FDA imposes detailed and specific requirements on devices approved for marketing under the PMA process	4
2. Preemption appropriately serves to safeguard the integrity of the PMA process	8
B. The 510(k) Process Similarly Results in the Imposition of Comprehensive Federal Requirements Entitled to Preemptive Effect	11
CONCLUSION	13

TABLE OF AUTHORITIES

Cases	Page
Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995), *rehearing denied* January 16, 1996	2, 3
King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993)	2
Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 2288 (U.S. Feb. 20, 1996) (No. 95-1323)	2, 3, 9
Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993)	2
Statutes & Regulations	
21 C.F.R. § 803.1	6
21 C.F.R. § 807.81(a)	12
21 C.F.R. § 808.1(d)	8, 12
21 C.F.R. 814.20	6
21 C.F.R. § 814.44	6
21 C.F.R. § 814.80	7
21 C.F.R. § 814.84	7
21 U.S.C. § 360c	4, 5
21 U.S.C. 360c-360*l*	1
21 U.S.C. § 360e(a)	5
21 U.S.C. § 360e(b)	5
21 U.S.C. § 360e(c)	2, 6
21 U.S.C. § 360e(d)	6
21 U.S.C. § 360e(e)	7
21 U.S.C. § 360i(b)	6
21 U.S.C. § 360j	5
21 U.S.C. § 360k	2, 3, 8, 12
43 Fed. Reg. 18661 (1978)	9
45 Fed. Reg. 67323 (1980)	9
46 Fed. Reg. 46394 (1981)	2
59 Fed. Reg. 64287 (1994)	11
Miscellaneous	
H.R. Rep. No. 808, 101st Cong., 2d Sess. 25 (1990)	11
H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976)	10
S. Rep. No. 33, 94th Cong., 1st Sess. 18 (1976)	10

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BRIEF OF *AMICUS CURIAE* COLLAGEN CORPORATION IN SUPPORT OF PETITIONER AND CROSS-RESPONDENT MEDTRONIC, INC.

INTEREST OF *AMICUS CURIAE*

Amicus curiae Collagen Corporation ("Collagen") produces Zyderm® Collagen Implant ("Zyderm"), a prescription-only product used by physicians to treat soft-tissue skin defects. Like the Model 4011 cardiac pacemaker lead at issue in this case, Zyderm has been classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*. However, the Model 4011 lead and Zyderm took different regulatory paths to the market-

place. The FDA granted the Model 4011 lead premarket clearance pursuant to 21 U.S.C. § 360(k) (the "510(k) process") upon finding that it was substantially equivalent to a device already on the market. Pet. App. 6a. But because no medical device similar to Zyderm had been marketed prior to enactment of the MDA, Zyderm was subject to the stringent premarket approval process under 21 U.S.C. § 360e(c) (the "PMA process"). After a detailed investigation, the FDA found Zyderm to be safe and effective and approved it for marketing. 46 Fed. Reg. 46394 (1981).

Zyderm now has been on the market for 15 years. During this time, some patients treated with Zyderm have sued Collagen, alleging that they suffered injurious adverse reactions. Such plaintiffs typically seek damages under common law theories of negligence and strict liability similar to those asserted by cross-petitioners Lohr against petitioner Medtronic, Inc., in this case. Until quite recently, reviewing courts were unanimous in holding that all or most such state-law based claims against Collagen are precluded by the MDA's preemption provision, 21 U.S.C. § 360k(a), which bars the states from imposing "any requirement" different from or in addition to applicable federal requirements. *See, e.g., Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 2288 (U.S. Feb. 20, 1996) (No. 95-1323); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S.Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993). Late last year, however, the Ninth Circuit rejected and departed from these holdings. Reasoning that common law tort rules do not impose "requirements" within the meaning of 21 U.S.C. § 360k(a), the Ninth Circuit held flatly that the MDA does not preempt *any* claims rooted in state common law. *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *rehearing denied* January 16, 1996. Collagen intends to file a petition for certiorari seeking review of the Ninth Circuit's aberrant decision in *Kennedy*.

Both parties in the instant case have identified *Kennedy* as establishing a circuit conflict warranting review. Pet. 16 n.11; Cross-Pet. 11 n.2, 17 n.11, 20. The Court in this case presumably will resolve this conflict by deciding, as a threshold matter, whether state common law imposes "requirements" within the meaning of 21 U.S.C. § 360k(a). This decision will directly affect the Court's subsequent disposition of *Kennedy*. Furthermore, if the Court concludes in this case that state common law does impose "requirements," the Court will proceed to consider the scope of MDA preemption as applied to claims relating to medical devices cleared for marketing under the 510(k) process. The Court's analysis of this issue also is likely to have a direct or indirect bearing upon cases, like *Kennedy* and *Mitchell*, that deal with claims relating to medical devices found to be safe and effective and approved for marketing under the PMA process. Accordingly, Collagen has an obvious and substantial interest in the outcome of this case, and the parties have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

This brief is narrow in focus. Petitioner Medtronic and various *amici* will demonstrate, *inter alia*, that state common law imposes "requirements" within the meaning of 21 U.S.C. § 360k(a) and that such requirements are different from and in addition to the extensive federal requirements governing Class III medical devices, like the Model 4011 cardiac pacemaker lead, that have been cleared for marketing pursuant to the 510(k) process. Collagen will not burden the Court with redundant argumentation on these points. Collagen believes, however, that it will be helpful to the Court, in considering the issues in this case, to understand not only the 510(k) process but the PMA process as well. This brief discusses the latter process and in doing so seeks to shed light on the matter of MDA preemption generally.

The FDA uses the PMA process to determine the safety and effectiveness of new Class III medical devices. Upon

finding a medical device to be safe and effective pursuant to the PMA process, the FDA approves the device for marketing subejct to detailed and specific requirements relating to, *inter alia*, design, manufacturing, packaging, and labeling. A major purpose of MDA preemption is to prevent the states from second-guessing or undermining this process by attempting to impose different or additional requirements of their own.

The PMA process and the 510(k) process differ, but the end results of the two processes are essentially similar: the FDA permits the medical device to go to market subject to numerous federal requirements in the form of both specific conditions and general regulatory controls. Under the MDA, these requirements have preemptive effect.

ARGUMENT

FEDERAL REQUIREMENTS PLACED UPON MEDICAL DEVICES PURSUANT TO THE MEDICAL DEVICE AMENDMENTS OF 1976 PREEMPT STATE LAW

A. Requirements Imposed on Medical Devices Found to Be Safe and Effective and Approved for Marketing Pursuant to the PMA Process Have Preemptive Effect

1. *The FDA imposes detailed and specific requirements on devices approved for marketing under the PMA process*

New "Class III devices must generally undergo premarket approval (PMA) before the FDA will allow them into the marketplace." Pet. App. 4a. The statutory objective of the PMA process is to ensure that the device affords a "reasonable assurance of safety." 21 U.S.C. § 360c(1)(c). Before the FDA approves a Class III device for marketing pursuant to the PMA process, it must determine that the device is safe and effective with respect to (1) the persons for whose use the device is

intended and (2) the conditions of use prescribed, recommended, or suggested in the labeling of the device. 21 U.S.C. § 360c(2). In making this determination, the FDA weighs any probable benefit to health from the use of the device against any probable risk of injury or illness. *Id.*

The PMA process is not the exclusive means by which Class III medical devices enter the market. The MDA provides three alternative routes to marketability: premarket approval is not required for (1) devices on the market prior to the effective date of the MDA, (2) devices, like the Model 4011 lead at issue in this case, found to be substantially equivalent to a device already on the market, or (3) devices entitled to the investigational device exemption. *See* 21 U.S.C. §§ 360e(b)(1)(A) and (B), 360j(g). But premarket approval is the statutory paradigm, and "the MDA contemplates that most Class III devices will reach the market through the PMA process." Pet. App. 4a; *see* 21 U.S.C. § 360e(a).

The PMA process entails an exhaustive investigation into safety and effectiveness. An applicant who seeks the FDA's approval to market a Class III device must provide:

> (A) full reports of all information, published or known to . . . the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
>
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing . . . of such device;
>
> (D) . . . adequate information to show that . . . such device fully meets [pertinent] performance standard[s] . . .;
>
> (E) . . . samples of such device . . .;
>
> (F) specimens of the labeling proposed to be used for such device; and

> (G) such other information . . . as the [FDA] . . . may require.

21 U.S.C. § 360e(c)(1).

The application for marketing approval also must include *inter alia*, a "general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended," an "explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device," and a "description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended." 21 C.F.R. § 814.20(b)(3). In addition, the application must be periodically updated "with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20 (e).

A completed application must be reviewed by a panel of experts. 21 U.S.C. § 360e(c)(2). After considering the panel's report and recommendation, the FDA will grant the application only if it finds reasonable assurance that the device is safe and effective, determines that the manufacturing and processing methods and facilities are satisfactory, and concludes that the proposed labeling is not false or misleading in any manner. 21 U.S.C. § 360e(d)(2); *see also* 21 C.F.R. § 814.44.

The FDA actively monitors devices after they have been approved for marketing. Both the manufacturer of the device and the health care providers who use it have a duty to report any information that reasonably suggests the device has caused injury. 21 U.S.C. § 360i(b); 21 C.F.R. § 803.1(a). The manufacturer also must periodically furnish information about "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device" and "[r]eports in the

scientific literature concerning the device." 21 C.F.R. § 814.84(b)(2). Marketing approval will be withdrawn if the FDA finds, *inter alia*, that the "device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling," that "the application contained or was accompanied by an untrue statement of a material fact," or that the labeling "is false or misleading in any particular." 21 U.S.C. § 360e(e)(1).

Once a medical device has been approved for marketing under the PMA process, it remains subject not only to active monitoring but also to tight regulatory controls. Some of these controls apply across the board to all Class III medical devices. The FDA's regulations relating to good manufacturing practice and labeling, discussed by the Eleventh Circuit in this case, are examples. *See* Pet. App. 30a-33a. Other controls, however, are device-specific, consisting of elaborate restrictions on the manufacture, distribution, and sale of a device after it has been approved for marketing.

A PMA approval order represents a license to market the approved medical device strictly in accordance with conditions specified by the FDA to ensure safety and effectiveness. By regulation, "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. In turn, the approval order typically sets forth or incorporates a laundry list of such conditions. The FDA's approval order for Zyderm is a case in point. That order set forth numerous "conditions of approval," including the following:

> *PMA Supplements. Before making any change that may affect the safety or effectiveness* of the device, submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:
>
> (1) new indications for use;

(2) labeling changes;

(3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;

(4) changes in sterilization procedures;

(5) changes in packaging;

(6) changes in the performance or design specifications, circuits parts, components, accessories, ingredients, or physical layout of the device.

Appendix, *infra*, at 4a (emphasis in original).

This means that Collagen, in producing and selling Zyderm, must adhere to all the specifications in its PMA application relating to indications for use, proposed labeling, manufacturing methods and facilities, sterilization procedures, packaging, ingredients, and performance and design. Other medical devices found to be safe and effective and approved for marketing pursuant to the PMA process are made subject to similar conditions. In this way, the FDA transmutes the specifications in a PMA application into binding federal requirements.

2. *Preemption appropriately serves to safeguard the integrity of the PMA process*

In this case, the Court must construe the MDA's express preemption provision, 21 U.S.C. § 360k(a). That statute provides that a state may not impose any requirement with respect to a medical device "(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." By regulation, the FDA has construed this statute as according preemption "when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d).

Respondents Lohr argue, with respect to the Model 4011 lead, that there is no federal "requirement" entitled to preemption under the statute so construed. As we show below, that argument is wrong. But is is useful to consider the issue first in the context of a device that has been approved for marketing pursuant to the PMA process. In that context, the existence of federal requirements is plain. In the first place, as the FDA itself has explained, "[f]or a device classified in Class III . . . , the counterpart FDA requirement [is] the requirement that the product have premarket approval." 43 Fed. Reg. 18661, 18664 (1978); *see also* 45 Fed. Reg. 67323 (1980). Thus "the premarket approval process constitutes a 'specific requirement' for purposes of 21 C.F.R. § 808.1(d) and 21 U.S.C. § 360k(a)." *Mitchell*, 67 F.3d at 1279. *See also id.* at n.6. (citing decisions in at least five other circuits reaching the same result). In addition, the comprehensive conditions accompanying a PMA approval order constitute "specific requirements applicable to a particular device." 21 C.F.R. § 808.1(d). Under the statute, these detailed and device-specific requirements also have preemptive effect.

Preemption safeguards the integrity of the PMA process. A PMA approval order represents the FDA's determination, following a lengthy and careful review process, that the approved medical device is safe and effective when manufactured, distributed, and sold in accordance with the conditions set forth therein. The federal regulatory process leading to that determination is both extensive and exhaustive. Once an approval order has been issued, the manufacturer remains subject to continued close federal scrutiny but is free to produce and sell the device without state interference or oversight. In this way, the states are precluded from second-guessing or undermining PMA approval orders.

Congress thereby has struck a balance that avoids both under-regulation and over-regulation. This was by express design. Congress developed the MDA as

> a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in the medical device industry are not stifled by unnecessary restrictions.

H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Congress intended preemption to play a vital role in achieving this balance.

Congress was fully aware of "the importance of the small innovative manufacturer [like Collagen] in the invention and development of new medical devices and the inability of these firms, because of limited financial resources, to sustain the high level of administrative costs demanded of a highly regulated industry." S. Rep. No. 33, 94th Cong., 1st Sess. 18 (1976). Congress determined that extraordinarily extensive federal oversight is necessary to ensure the safety and effectiveness of newly developed medical devices. But Congress further concluded that an additional layer of state-law requirements would be both unnecessary and counterproductive, noting that "interstate commerce would be unduly burdened" by the imposition of "differing requirements applicable to a medical device . . . by jurisdictions other than the Federal government." H.R. Rep. No. 853 at 45. The broadly worded MDA preemption statute grew out of these concerns. It ensures that firms like Collagen, which have met the burden of demonstrating safety and effectiveness under the PMA process, will be subject only to those regulatory requirements that Congress and the FDA have chosen to prescribe.

B. The 510(k) Process Similarly Results in the Imposition of Comprehensive Federal Requirements Entitled to Preemptive Effect

The Model 4011 cardiac pacemaker lead at issue in this case entered the market via the 510(k) process. The explicit focus of the FDA's inquiry under the 510(k) process is whether the medical device is substantially equivalent to another device already on the market, but this also includes "some inquiry into the safety and effectiveness of [the] new device." 59 Fed. Reg. 64287, 64288 (1994). Although proving substantial equivalence may require the submission and evaluation of considerable data, the FDA's investigation ordinarily is not as exhaustive or demanding as that entailed by the PMA process.

This does not mean that a device cleared for marketing under the 510(k) process is any less safe or effective than one approved under the PMA process. To the contrary, the 510(k) process represents a congressional judgment that if a new device is substantially equivalent to one that has demonstrated its own safety and effectiveness by withstanding the test of time, the new device itself is sufficiently safe and effective to be placed on the market. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 25 (1990). At the conclusion of either the 510(k) process or the PMA process, therefore, the medical device that is permitted to enter the market is believed to be both safe and effective.

Moreover, notwithstanding their other differences, the two regulatory processes share at least two crucial similarities. *First*, each process embodies a set of federal requirements that must be met before a device may be marketed. Under the MDA, those federal requirements preempt state laws that would impose different or additional restrictions on marketability. *Second*, as is the case

under the PMA process, the final order clearing a device for marketing under the 510(k) process typically specifies that the applicant may not make any changes in, for example, labeling, manufacturing, or design that might affect safety or effectiveness. *See* 21 C.F.R. § 807.81(a). These conditions on continued marketability, like those contained in the typical PMA approval order, constitute further binding federal requirements. They are "specific requirements applicable to a particular device," 21 C.F.R. § 808.1(d), and as such are entitled to preemption under the MDA.

The MDA preemption statute is broadly worded. The statute expressly preempts competing state requirements relating not only to "safety and effectiveness" but also to "any other matter included in a [federal] requirement." 21 U.S.C. § 360k(a)(2). Thus it is the existence of a federal requirement, not the finding of safety and effectiveness, that triggers preemption under the statute. As petitioner Medtronic will show, the Model 4011 lead is subject to numerous such requirements, including a requirement that there be no change in design affecting safety or effectiveness. Under the MDA preemption statute, the states may not impose different or additional requirements of their own.

CONCLUSION

The judgment of the Eleventh Circuit should be reversed insofar as it allows respondent Lohrs' design claims to go to trial; the judgment otherwise should be affirmed.

Respectfully submitted,

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APPENDIX

APPENDIX

[LOGO]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

[Jul. 22, 1981]

Bruce B. Pharriss, Ph.D.
Vice President of
Scientific Affairs
Collagen Corporation
2455 Faber Place
Palo Alto, California 94303

Re: P800022
Zyderm™ Collagen Implant
Filed: May 2, 1980
Amended: November 10, 1980
February 24, March 19, April 10,
April 16, and May 7, 1981

Dear Dr. Pharriss:

The Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) for the Zyderm™ Collagen Implant (hereinafter referred to as Zyderm™). The PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin production and marketing of the device upon receipt of this letter.

FDA will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. In addition, the notice will state that a copy of all approved final labeling (which may be a draft of the final labeling) is available for public inspection at the Bureau of Medical Devices. Within thirty days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may obtain review of this decision by requesting an opportunity for administrative review, either through a hearing or

review by an independent advisory committee under section 515(g) of the Federal Food, Drug, and Cosmetic Act.

FDA approval is subject to full compliance with the conditions described in the enclosure and the following:

1. The sale, distribution, and use of this device is to be restricted to prescription use in accordance with 21 CFR 801.109.

2. The post-approval (Phase IV) studies under your immunology protocol ZC-980 shall be extended from 3 to 12 months, and shall include determination of antibody levels in patients at 6 and 12 months after initiation of Zyderm™ treatment and the results submitted in the annual report. The studies shall report experimental details, such as the frequency and the amount of Zyderm™ injected, and the dates of blood sample collection from each patient. Patients selected under this protocol shall represent a cross section of patients receiving Zyderm™.

   In addition to Zyderm™, native and denatured bovine skin type I collagen (not treated by pepsin) shall be used to determine the levels of anti-Zyderm™ antibodies in the patients.

   Data on the cross-reactivity of Zyderm™ antibodies with type III collagen shall be provided, since human skin contains both type I and type III collagen.

   Circulating Zyderm™-antibody complexes shall be determined in fresh blood samples, and their levels demonstrated to be in the same range as those from individuals not exposed to Zyderm™ treatment.

3. In the post-approval (Phase IV) period, Zyderm™-treated patients shall be monitored for the occurrence of adverse reactions at 6-month intervals during a 3-year period, and the follow-up data submitted in the annual report to the FDA.

   FDA will review these data and determine whether or not the post-approval monitoring of Zyderm™ should be continued at the present level.

4. A patient information manual shall be distributed with the device.

All stated requirements are subject to change upon publication of a final premarket approval procedural regulation. Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a product which is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

All required documents must be submitted in duplicate to the Bureau of Medical Devices, Document Control Center (HFK-20), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

If you have any questions concerning the approval of this application or its conditions, please contact Carl A. Larson, Ph.D., at (301) 427-7156.

Sincerly,

/s/ Robert G. Britain
for VICTOR ZAFRA
Acting Director
Bureau of Medical Devices

Enclosure

Conditions of Approval

Approved Labeling. As soon as possible, and prior to commercial distribution of your device, submit two copies of all approved labeling in final printed form.

Advertisement. No advertisement for this device shall recommend or imply that the device may be used for any use that is not mentioned in the approved labeling for the device. All written promotional material shall state the indications, contraindications, warnings, precautions and adverse effects of the device.

PMA Supplements. Before making any change that may affect the safety or effectiveness of the device, submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:

(1) new indications for use;

(2) labeling changes;

(3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;

(4) changes in sterilization procedures;

(5) changes in packaging; and

(6) changes in the performance or design specifications, circuits parts, components, accessories, ingredients, or physical layout of the device.

Changes in labeling, manufacturing, sterilization, packaging, or performance or design specification which enhance safety of the device or safety in the use of the device may be placed into effect by the sponsor prior to the receipt of a written FDA approval of the supplemental PMA provided:

(1) the submission is plainly marked on the mailing cover and on the supplement "Special PMA Supplement—Changes Being Effected";

(2) the supplemental PMA provides a full explanation of the basis for the changes;

(3) the applicant has received acknowledgement from the Bureau of Medical Devices of receipt of the supplement; and

(4) the supplement specifically identifies the date that such changes are being effected.

Specific examples of changes permitted are:

(1) addition of warnings, contraindications, or side effects;

(2) deletion of misleading, false, or unsupported indications; and

(3) changes in the manufacturing process or quality controls that provide additional assurance of purity, identity, strength, or reliability.

FDA may, as experience permits, issue guidelines listing specific types of changes that do not require FDA approval prior to implementation.

Post-Approval Reports. Continued approval of your device is contingent upon the submission of post-approval reports to the Bureau of Medical Devices at intervals of one year from the date of this letter. The required contents of these reports will be described in the FEDERAL REGISTER in the premarket approval procedural regulation which will be published in the future. Until this regulation is published in final form, each periodic report shall consist of information that previously has not been submitted as part of a PMA or supplemental PMA and which you have obtained since the last post-approval report or since receipt of this letter, whichever is later:

1. A summary and bibliography of reports in the scientific literature involving the device and unpublished reports of *in vitro*, animal and clinical experience studies, investigations, and tests con-

ducted by, reported to, or reasonably available to you involving the device or a related device.

If, after reviewing the summary and bibliography, FDA concludes that it needs a copy of the published and unpublished reports themselves, FDA will notify you that copies of such reports shall be submitted.

2. Written promotional material.

3. A description of changes made in the device not previously submitted in a supplemental PMA.

Adverse Reaction and Device Defect Reporting.

You shall submit a written report to the Bureau of Medical Devices within ten days after you receive or have knowledge of information about:

(1) a mixup of the device or its labeling with another article;

(2) any significant chemical, physical, or other change or deterioration in the device, or any failure of one or more of the devices to meet the specifications established in the application; and

(3) any adverse reaction, side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence, or severity thereof, associated with any clinical use, study, investigation, or test of the device, which has been determined to be attributable to the device or has not been addressed by the device labeling. The term "unexpected" refers to conditions or developments not previously identified in the application.

Note: All conditions of approval are subject to change upon publication of a final premarket approval regulation.

(10) (11)

Supreme Court, U.S.
FILED
MAR 13 1996
CLERK

Nos. 95-754 & 95-886

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner,

v.

LORA LOHR, *et vir,*

Respondent, and
Cross Petitioner.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

MOTION FOR LEAVE TO FILE A BRIEF AND BRIEF FOR TWO PRODUCTS LIABILITY LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY

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March 11, 1996

* *Counsel of Record*

37 pp

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The undersigned respectfully move for leave to file the attached brief *amicus curiae* in support of neither party. Counsel for Respondent Lora Lohr consented to the filing of this brief, but Counsel for Petitioner Medtronic did not.[1/]

The undersigned teach and write in the area of tort law and products liability and are especially interested in the rapidly accelerating use of federal preemption as a defense.[2/]

[1/] At the time that this motion and brief were finalized for printing, counsel for Medtronic represented to the undersigned that he still had not received final instructions from his client in response to our request of January 29, 1996.

[2/] *E.g.*, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 Wm. & Mary L. Rev. 903 (1996).

The attached brief offers an approach that neither Party is likely to elaborate. Medtronic will argue that the preemption provision in the Medical Device Amendments (MDA), 21 U.S.C. § 360k(a), completely insulates manufacturers from products liability claims; Ms. Lohr will argue that the MDA preempts no tort claims, at least not those claims against manufacturers of medical devices subject to premarket clearance. The proposed *amicus* brief suggests a middle position, encouraging the Court to recognize a limited preemption defense to tort claims. Although not consistent with either Party's ideal litigating position, this formulation would be preferable to their opponent's extreme alternative.

In addition, the proposed *amicus* brief addresses some of the broader implications of the instant case. The Court's resolution of these petitions will have immediate and profound repercussions in other products liability litigation.

Respectfully submitted,

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TABLE OF CONTENTS

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

INTEREST OF *AMICI CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 3

I. LOWER COURTS HAVE DEVELOPED SEVERAL COMPETING CONCEPTIONS OF PREEMPTION 5

A. The Strong Version: Preemption as Foreclosing Tort Remedies Altogether . . 6

B. An Intermediate Version: Preemption as Displacing State Tort Law Standards . . 10

C. The Weak Version: Proof of Compliance as a Predicate for the Defense 14

II. PREEMPTION SHOULD BE INTERPRETED AS THE GOVERNMENT STANDARDS DEFENSE 17

CONCLUSION 25

TABLE OF AUTHORITIES

Cases:

Abbot v. American Cyanamid Co.,
844 F.2d 1108 (4th Cir.),
cert. denied, 488 U.S. 908 (1988) 21

Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.,
959 F.2d 158 (10th Cir.),
vacated, 113 S. Ct. 314 (1992),
reinstated, 981 F.2d 1177 (10th Cir.),
cert. denied, 114 S. Ct. 60 (1993) 20

Atascadero State Hosp. v. Scanlon,
473 U.S. 234 (1985) 17

Bailey v. Johnson,
48 F.3d 965 (6th Cir. 1995) 7

Bammerlin v. Navistar Int'l Transp. Corp.,
30 F.3d 898 (7th Cir. 1994) 14

Bieneman v. City of Chicago,
864 F.2d 463 (7th Cir. 1988),
cert. denied, 490 U.S. 1080 (1989) 11

Boyle v. United Technologies Corp.,
487 U.S. 500 (1988) 21

Butcher v. Robertshaw Controls Co.,
550 F. Supp. 692 (D. Md. 1981) 16

Caterpillar Inc. v. Williams,
482 U.S. 386 (1987) 8

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505 U.S. 504 (1992) . . . . . *passim*

Cort v. Ash,
422 U.S. 66 (1975) 18

CSX Transp., Inc. v. Easterwood,
113 S. Ct. 1732 (1993) 4

Daily Income Fund, Inc. v. Fox,
464 U.S. 523 (1984) 18

Davis v. Brunswick Corp.,
854 F. Supp. 1574 (N.D. Ga. 1994) 11

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867 F.2d 1080 (8th Cir.),
cert. denied, 492 U.S. 927 (1994) 8

Eimers v. Honda Motor Co.,
785 F. Supp. 1204 (W.D. Pa. 1992) 12

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496 U.S. 72 (1990) 4

Ferebee v. Chevron Chem. Co.,
736 F.2d 1529 (D.C. Cir.),
cert. denied, 469 U.S. 1062 (1984) 17

Fogal v. Steinfeld,
620 N.Y.S.2d 875 (Sup. Ct. 1994) 9

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Freightliner Corp. v. Myrick,
115 S. Ct. 1483 (1995) 4

Gile v. Optical Radiation Corp.,
22 F.3d 540 (3d Cir.),
cert. denied, 115 S. Ct. 429 (1994) 6, 18

Ginochio v. Surgikos, Inc.,
864 F. Supp. 948 (N.D. Cal. 1994) 18

Gonzales v. Surgidev Corp.,
899 P.2d 576 (N.M. 1995) 11

Helms v. Sporicidin Int'l,
871 F. Supp. 837 (E.D.N.C. 1994) 7

Hernandez-Gomez v. Leonardo, 884 P.2d 183
(Ariz. 1994), *vacated sub nom.*,
Volkswagen of Am., 115 S. Ct. 1819 (1995) 17

Hodges v. Delta Airlines, Inc.,
44 F.3d 334 (5th Cir. 1995) 21

Hunsaker v. Surgidev Corp.,
818 F. Supp. 744 (M.D. Pa. 1992),
aff'd mem., 5 F.3d 1489 (3d Cir. 1993) . . . 10

Hurley v. Lederle Lab.,
863 F.2d 1173 (5th Cir. 1988) 16

Hurt v. Dow Chem. Co.,
963 F.2d 1142 (8th Cir. 1992) 8

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440 S.E.2d 38 (Ga. App. 1993),
aff'd in part, 450 S.E.2d 671 (Ga. 1994) . . 8

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635 F.2d 987 (2d Cir. 1980),
cert. denied, 454 U.S. 1128 (1981) 7

International Longshoremen's Ass'n v. Davis,
476 U.S. 380 (1986) 9

Jenkins v. James B. Day & Co.,
634 N.E.2d 998 (Ohio 1994) 10

Kemp v. Pfizer, Inc.,
835 F. Supp. 1015 (E.D. Mich. 1993) 8, 18

King v. Collagen Corp.,
983 F.2d 1130 (1st Cir.),
cert. denied, 114 S. Ct. 84 (1993) 7

Landgraf v. USI Film Products,
114 S. Ct. 1483 (1994) 20

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559 N.Y.S.2d 788 (Sup. Ct. 1990) 9

Lohr v. Medtronic, Inc.,
56 F.3d 1335 (11th Cir. 1995),
cert. granted, 116 S. Ct. 806 (1996) 6

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624 F.2d 1373 (5th Cir. 1980) 12

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47 F.3d 124 (4th Cir. 1995) 10, 14

Mears v. Marshall,
905 P.2d 1154 (Or. App. 1995) 6

Mendes v. Medtronic, Inc.,
18 F.3d 13 (1st Cir. 1994) 6, 18

Merrell Dow Pharmaceuticals, Inc. v. Thompson,
478 U.S. 804 (1986) 7

Metropolitan Life Ins. Co. v. Taylor,
481 U.S. 58 (1987) 8

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46 F.3d 1316 (3d Cir.),
cert. denied, 116 S. Ct. 67 (1995) 7, 8

Miller v. E.I. DuPont de Nemours & Co.,
880 F. Supp. 474 (S.D. Miss. 1994) 7

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858 F. Supp. 1426 (C.D. Cal. 1994) 11, 21

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784 F.2d 91 (2d Cir.),
cert. denied, 479 U.S. 872 (1986) 7

Moss v. Parks Corp.,
985 F.2d 736 (4th Cir.),
cert. denied, 113 S. Ct. 2999 (1993) 10, 11

Mulhern v. Outboard Marine Corp.,
432 N.W.2d 130 (Wis. App. 1988) 9

National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) 11

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985 F.2d 516 (11th Cir.),
cert. denied, 114 S. Ct. 300 (1993) 7

Reeves v. AcroMed Corp.,
44 F.3d 300 (5th Cir.),
cert. denied, 115 S. Ct. 2251 (1995) 6, 8

Reiter v. Zimmer, Inc.,
830 F. Supp. 199 (S.D.N.Y. 1993) 12

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865 F. Supp. 1210 (E.D. La. 1994) 8

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688 F. Supp. 475 (S.D. Ind. 1988) 12

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531 N.W.2d 793 (Mich. App. 1995) 9

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969 F.2d 72 (4th Cir. 1992) 12

Shots v. CSX Transp., Inc.,
38 F.3d 304 (7th Cir. 1994) 7

Shumaker v. C.R. Bard, Inc.,
1996 U.S. Dist. LEXIS 822 (D. Mass. 1996) 8

Silkwood v. Kerr-McGee Corp.,
464 U.S. 238 (1984) 4, 17

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961 F.2d 1330 (7th Cir.),
cert. denied, 113 S. Ct. 327 (1992) 10

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718 F.2d 553 (3d Cir. 1983) 12

Stewart v. International Playtex, Inc.,
672 F. Supp. 907 (D.S.C. 1987) 10

St. Louis S.W. Ry. v. Malone Freight Lines,
39 F.3d 864 (8th Cir. 1994),
cert. denied, 115 S. Ct. 1963 (1995) 15

Strong v. Telectronics Pacing Sys., Inc.,
891 F. Supp. 401 (W.D. Mich. 1994) 8

Suter v. Artist M.,
112 S. Ct. 1360 (1992) 18

Swift v. United States,
866 F.2d 507 (1st Cir. 1989) 12

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865 F. Supp. 37 (D. Mass. 1994),
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Texas Indus., Inc. v. Radcliff Materials, Inc.,
451 U.S. 630 (1981) 18

Violette v. Smith & Nephew Dyonics, Inc.,
62 F.3d 8 (1st Cir. 1995) 11

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735 F. Supp. 1030 (S.D. Fla. 1990) 11

Weinberger v. Bentex Pharmaceuticals, Inc.,
412 U.S. 645 (1973) 14

Worm v. American Cyanamid Co.,
5 F.3d 744 (4th Cir. 1993) 10

Statutes and Regulations:

15 U.S.C. § 1334(b) (1994) 19

21 U.S.C. § 360k(a) (1994) 2

42 U.S.C. §§ 300aa-22(b), 300aa-23(d) 19

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James A. Henderson, Jr., Richard N. Pearson &
John A. Siliciano, The Torts Process (4th ed. 1994) 1

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37 Wm. & Mary L. Rev. 903 (March 1996) . . . 1, 18

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49 Food & Drug L.J. 183 (1994) 1

Richard N. Pearson, *The Florida Medicaid Third-Party Liability Act*, 46 Fla. L. Rev. 609 (1994) . 1

Rest. (3d) Torts: Prods. Liab. (1995) 10

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BRIEF FOR TWO PRODUCTS LIABILITY LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY

INTEREST OF *AMICI CURIAE*

Amici teach and write in the area of tort law and products liability,[1] and are especially interested in the rapidly accelerating use of federal preemption as a defense.[2]

---

[1] *See, e.g.*, James A. Henderson, Jr., Richard N. Pearson & John A. Siliciano, The Torts Process (4th ed. 1994); Richard N. Pearson, *The Florida Medicaid Third-Party Liability Act*, 46 Fla. L. Rev. 609 (1994).

[2] *See, e.g.*, Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 Wm. & Mary L. Rev. 903 (March 1996); Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 Food & Drug L.J. 183 (1994).

This case presents an important opportunity to clarify how courts should apply the preemption provisions that appear in a variety of federal safety statutes to tort litigation. The questions presented by the parties broadly ask the Court to determine whether and to what extent federal law preempts tort claims against manufacturers of medical devices. *Amici* have filed this brief to explain some of the notable difficulties that lower courts have encountered when addressing the increasingly popular preemption defense. The Court's resolution of the instant petitions will have significant consequences for numerous products liability cases.

SUMMARY OF ARGUMENT

The courts below correctly recognized some of the difficulties that attend the application of the preemption defense. The district court granted summary judgment for defendant, dismissing all of the plaintiffs' claims against Medtronic, Inc., the manufacturer of the allegedly defective pacemaker implanted in Ms. Lohr. The United States Court of Appeals for the Eleventh Circuit accepted Medtronic's primary argument that the Medical Device Amendments (MDA)[3] preempted tort claims under Florida state law. Nonetheless, the court reversed judgment with regard to plaintiffs' negligent design and strict liability claims because it held that the Food and Drug Administration (FDA) had not imposed any particular design requirements when it cleared this device for commercial marketing. The Eleventh Circuit, however, affirmed dismissal of the plaintiffs' negligent

[3] *See* 21 U.S.C. § 360k(a) (1994).

manufacture and failure-to-warn claims, rejecting Ms. Lohr's argument that the preemption defense should not apply insofar as these claims were premised on violations of applicable federal statutory standards. Pet. App. 13a-14a.

As illustrated by the instant case, there are several still unresolved questions concerning the proper application of the preemption defense under the MDA and similar safety statutes. Because the scope of federal preemption turns primarily on matters of statutory construction, the subject defies simple unitary treatment. Indeed, as applied by the courts, the preemption defense lacks any single, coherent meaning. Nonetheless, these statutory provisions pose important recurring problems. *Amici* suggest alternatives to the exaggerated reading of *Cipollone* that has been adopted by a number of courts and was suggested by the Eleventh Circuit in this case. In particular, this Court should clarify that *Cipollone* announced a federal common law rule accepting the "government standards" defense, a defense that would absolve a company of liability only upon a showing of compliance with all relevant safety requirements.

ARGUMENT

Federal preemption arguments in tort actions have proliferated over the last few years. This Court's decision in *Cipollone v. Liggett Group, Inc.*,[4] triggered a notable upsurge in the successful use of preemption as a defense to

[4] 505 U.S. 504 (1992).

products liability lawsuits. During the decade preceding *Cipollone*, the Court expressed a marked reluctance to find preemption of tort claims,[2] but its decisions from the last several Terms suggest a significant reversal in this attitude.[3] A number of lower courts apparently have viewed *Cipollone* and its progeny as a mandate to dismantle the protections of state tort law, even in extreme situations where a defendant has not complied with the federal requirements that are being given preemptive effect.

Almost four years now have elapsed since *Cipollone* was decided. As feared by a number of the Justices in that case, lower courts have struggled when applying the plurality's judgment in other contexts. Preemption provisions appear in statutes regulating, inter alia, medical devices, pesticides and other hazardous chemicals, and various modes of transportation. Because these provisions express congressional intent in different terms, and in some cases are accompanied by savings clauses of varying breadth, lower courts have encountered difficulties interpreting the proper scope of federal preemption. A number of courts have read *Cipollone* quite expansively, however, finding preemption of most or all tort claims, sometimes even where the defendants have not complied with the applicable federal safety requirements.

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[2] *See, e.g.*, English v. General Elec. Co., 496 U.S. 72, 80-86 (1990); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251-56 (1984).

[3] *See* Freightliner Corp. v. Myrick, 115 S. Ct. 1483, 1487-88 (1995); CSX Transp., Inc. v. Easterwood, 113 S. Ct. 1732, 1740-43 (1993); *Cipollone*, 505 U.S. at 524 (plurality).

Increasingly, defendants assert federal preemption as a defense in tort litigation involving, for example, medical devices and pesticides. This trend represents a departure from the traditional application of preemption as a barrier only to conflicting state and local legislation and regulation, and, more disturbingly, the use of the preemption defense in tort litigation sometimes immunizes defendants from liability irrespective of their conduct. Indeed, as argued herein, lower courts have misinterpreted *Cipollone* by finding broad preemption of tort claims under other federal safety statutes when this Court really had nothing more than the government standards defense in mind.

I. LOWER COURTS HAVE DEVELOPED SEVERAL COMPETING CONCEPTIONS OF PREEMPTION.

Although preemption of tort claims under various statutory provisions generally has been accepted, at least under some circumstances, important questions remain to be resolved. One of the most immediate quandaries concerns the practical consequence of a finding that one or more claims are preempted in a particular case. For instance, does preemption mean that failure-to-warn or other tort claims may never be brought against companies, or instead may a plaintiff sustain such a claim by introducing evidence of noncompliance with agency regulations? If the latter is true, then who bears the burden of proof if noncompliance is alleged; must the defendant prove compliance as a predicate for invoking a preemption defense, or does it become an element of the plaintiff's burden when attempting to assert a claim in the face of such a defense? More fundamentally, is such a defense even properly characterized as one based on "preemption"?

The lower courts have offered varying answers to these questions, suggesting three different conceptions of federal preemption as applied in the context of tort litigation. As more fully developed in the following sections, it is possible to differentiate between a "strong," "intermediate," and "weak" version of the preemption defense based in part on whether compliance with federal safety standards is relevant and which party shoulders the burden of proof on that issue. The choice of one among these competing conceptions of the preemption defense will have profound consequences for litigants in future tort cases.

A. The Strong Version: Preemption as Foreclosing Tort Remedies Altogether.

In the wake of *Cipollone*, several lower courts have suggested that preemption would completely cut off common law claims whenever federal safety requirements apply, whether or not a particular company has strictly complied with those requirements. This view is most noticeable in medical device decisions, including the instant case.[7/]

Under this extreme approach, a plaintiff could not seek compensatory damages for injuries resulting from a manufacturer's failure to abide by federal requirements. Plaintiffs would have no recourse under state tort law, and

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[7/] *See, e.g.*, Lohr v. Medtronic, Inc., 56 F.3d 1335, 1343 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (1996); Talbott v. C.R. Bard, Inc., 63 F.3d 25, 27-30 (1st Cir. 1995), *petition for cert. filed*, No. 95-1321 (Feb. 16, 1996); Reeves v. AcroMed Corp., 44 F.3d 300, 307 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); Mendes v. Medtronic, Inc., 18 F.3d 13, 17-19 (1st Cir. 1994); Mears v. Marshall, 905 P.2d 1154, 1166-67 (Or. App. 1995).

courts have consistently rejected arguments that a private right of action exists under any of the federal safety statutes.[8/] Similarly, a number of courts have rejected negligence per se claims premised on violations of federal requirements because otherwise, they conclude, plaintiffs could circumvent Congress' intent not to provide a private right of action under these federal statutes.[9/]

Under the strong version of preemption, even claims that agency approval was secured by the submission of incomplete or inaccurate data would be unavailable.[10/] Courts abiding by the strong version of preemption have squarely rejected the argument that allegations of fraud in procuring approval could defeat an applicable preemption

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[8/] *See* Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 810 (1986) (assuming without deciding that Congress intended to prohibit private enforcement of the Food, Drug and Cosmetic Act); Bailey v. Johnson, 48 F.3d 965, 967-68 (6th Cir. 1995); Montauk-Caribbean Airways, Inc. v. Hope, 784 F.2d 91, 97 (2d Cir.), *cert. denied*, 479 U.S. 872 (1986); *In re* "Agent Orange" Prod. Liab. Litig., 635 F.2d 987, 991-92 n.9 (2d Cir. 1980), *cert. denied*, 454 U.S. 1128 (1981).

[9/] *See, e.g.*, Miller v. E.I. DuPont de Nemours & Co., 880 F. Supp. 474, 480 (S.D. Miss. 1994); Helms v. Sporicidin Int'l, 871 F. Supp. 837, 839 (E.D.N.C. 1994).

[10/] *See, e.g.*, Michael v. Shiley, Inc., 46 F.3d 1316, 1328-29 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); Shots v. CSX Transp., Inc., 38 F.3d 304, 308 (7th Cir. 1994); King v. Collagen Corp., 983 F.2d 1130, 1139-40 (1st Cir.) (Aldrich, J., concurring), *cert. denied*, 114 S. Ct. 84 (1993); Papas v. Upjohn Co., 985 F.2d 516, 519 (11th Cir.) (per curiam), *cert. denied*, 114 S. Ct. 300 (1993).

defense, in part because otherwise such allegations would become routine and difficult to resolve.[11]

The strong conception of the defense resembles so-called "complete" preemption, a doctrine that has developed under the federal labor statutes. Complete preemption means that the displacement of state law by federal statute is such that a defendant could remove an action from state court under federal question jurisdiction, creating an exception to the well-pleaded complaint rule that would otherwise ignore federal issues raised defensively.[12] Although the existence of a parallel federal remedy originally was regarded as a prerequisite for complete preemption of a state law claim, such substitution apparently is no longer necessary to support removal.[13] Courts initially rejected arguments that federal safety statutes establish complete preemption, but several now have granted removal petitions on such a theory.[14]

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[11] *See Talbott*, 63 F.3d at 29-30; *Michael*, 46 F.3d at 1329; *Reeves*, 44 F.3d at 307; Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1021-22 (E.D. Mich. 1993); ICI Americas, Inc. v. Banks, 440 S.E.2d 38, 42-43 (Ga. App. 1993), *aff'd in relevant part*, 450 S.E.2d 671 (Ga. 1994).

[12] *See, e.g.*, Metropolitan Life Ins. Co. v. Taylor, 481 U.S. 58, 63-67 (1987); Franchise Tax Bd. v. Construction Laborers Vacation Trust, 463 U.S. 1, 24-28 (1983).

[13] *See, e.g.*, Caterpillar Inc. v. Williams, 482 U.S. 386, 391 n.4 (1987); Deford v. Soo Line R.R., 867 F.2d 1080, 1086 (8th Cir.), *cert. denied*, 492 U.S. 927 (1994).

[14] *See, e.g.*, Shumaker v. C.R. Bard, Inc., 1996 U.S. Dist. LEXIS 822, at *6-9 (D. Mass. Jan. 3, 1996); Richardson v. Advanced Cardiovascular Sys., Inc., 865 F. Supp. 1210, 1213-16 (E.D. La. 1994); Strong v. Telectronics Pacing Sys., Inc., 891 F. Supp. 401, 402-03 (W.D. Mich. 1994). *But see* Hurt v. Dow Chem. Co., 963 F.2d 1142, 1144-45 (8th Cir. 1992)

Similarly, according to some courts, preemption deprives them of subject matter jurisdiction over all tort actions within the preempted domain, apparently in the sense that a federal agency has been given exclusive jurisdiction over the matter.[15] This is similar to the effect of preemption under the National Labor Relations Act. Because Congress assigned exclusive jurisdiction over unfair labor practice claims to the NLRB, federal preemption strips state courts of their subject matter jurisdiction to hear claims of this sort.[16] This Court has emphasized, however, that its decision to vest exclusive jurisdiction in the NLRB "does not apply to pre-emption claims generally but only to those preemption claims that go to the State's actual adjudicatory or regulatory power as opposed to the State's substantive laws."[17] Nonetheless, some state courts have accorded a comparable effect to preemption provisions in federal safety statutes, treating these provisions as divesting them of jurisdiction over tort claims against products or activities that are subject to federal regulation.[18]

Of course, even if not properly regarded as an objection to jurisdiction or a basis for removal, the strong version of

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[15] *See, e.g.*, Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 40 (D. Mass. 1994), *aff'd*, 63 F.3d 25, 29-30 (1st Cir. 1995).

[16] *See* International Longshoremen's Ass'n v. Davis, 476 U.S. 380, 391 (1986).

[17] *Id.* at 391 n.9.

[18] *See, e.g.*, Ryan v. Brunswick Corp., 531 N.W.2d 793, 796 (Mich. App. 1995); Fogal v. Steinfeld, 620 N.Y.S.2d 875, 880 (Sup. Ct. 1994); Little v. Dow Chem. Co., 559 N.Y.S.2d 788, 790 (Sup. Ct. 1990); Mulhern v. Outboard Marine Corp., 432 N.W.2d 130, 134 (Wis. App. 1988).

preemption would support a defendant's motion to dismiss for failure to state a claim, and no set of proffered evidence or amended allegations could save any claims that fall within the preempted domain. Thus, the strong version of the preemption defense effectively forecloses tort remedies altogether.

B. An Intermediate Version: Preemption as Displacing State Tort Law Standards.

Under a less extreme view, federal preemption of tort claims would not completely cut off actions for damages, at least not in the event of noncompliance with federal standards.[19/] For example, several courts in earlier medical device cases explained that only the substantive duties imposed under state law are preempted.[20/] Under this view, preemption does not foreclose the availability of compensatory damages for personal injuries or other common law remedies, but it does mean that federal regulatory standards will trump tort law standards such as the general duty of care under negligence. Plaintiffs would not be able to invite judges and juries to second-guess, under the guise of

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19/ *See, e.g.*, Lowe v. Sporicidin Int'l, 47 F.3d 124, 130 (4th Cir. 1995); Worm v. American Cyanamid Co., 5 F.3d 744, 748 (4th Cir. 1993); Moss v. Parks Corp., 985 F.2d 736, 740 (4th Cir.), *cert. denied*, 113 S. Ct. 2999 (1993); Jenkins v. James B. Day & Co., 634 N.E.2d 998, 1003-05 (Ohio 1994).

20/ *See, e.g.*, Slater v. Optical Radiation Corp., 961 F.2d 1330, 1334 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992); Hunsaker v. Surgidev Corp., 818 F. Supp. 744, 751 (M.D. Pa. 1992), *aff'd mem.*, 5 F.3d 1489 (3d Cir. 1993); Stewart v. International Playtex, Inc., 672 F. Supp. 907, 910 (D.S.C. 1987); *see also* Rest. (3d) Torts: Prods. Liab. § 7, cmt. e (1995), at 198.

applying a manufacturer's common law duty of care, an agency's safety and utility determinations for products whose design and labeling the agency has either dictated by regulation or individually reviewed and approved.

Because many of the preemption provisions prohibit only "different" state requirements, courts reason that claims premised on noncompliance with the federal standard would not impose a different obligation under state tort law.[21/] The possibility that a company may be liable for violation of federal standards has provided courts with one way of reconciling statutory savings clauses (which preserve existing rights or remedies at common law) with express preemption provisions.[22/] The intermediate version of preemption may, therefore, be understood as nothing more than a choice-of-law principle, directing courts to select federal rather than state standards when resolving tort claims.[23/]

Plaintiffs would be able to recover under state law for injuries in the event that a manufacturer violated the conditions contained in any applicable product license or

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21/ *See, e.g.*, National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 993 (8th Cir. 1994); *Moss*, 985 F.2d at 740-41; Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1439 (C.D. Cal. 1994).

22/ *See, e.g.*, Bieneman v. City of Chicago, 864 F.2d 463, 471 (7th Cir. 1988), *cert. denied*, 490 U.S. 1080 (1989); Davis v. Brunswick Corp., 854 F. Supp. 1574, 1581 (N.D. Ga. 1994); Von Anhalt v. Delta Air Lines, Inc., 735 F. Supp. 1030, 1031 (S.D. Fla. 1990).

23/ *See* Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 10-12 (1st Cir. 1995); Gonzales v. Surgidev Corp., 899 P.2d 576, 582-83 (N.M. 1995). Although a failure to state a claim objection may be made as late as the trial on the merits, preemption understood merely as a choice-of-law objection would represent an affirmative defense which may be waived if not raised in a timely fashion.

regulation.[24] Indeed, in many jurisdictions, violations of federal requirements constitute negligence per se,[25] though not all jurisdictions recognize this rule.[26] Under the intermediate version of preemption being described here, courts essentially would allow only such negligence per se claims to go forward. Similarly, a fraud-on-the-agency claim might escape federal preemption, assuming it is otherwise available under state law.[27]

Preemption would not, however, depend on proof of compliance with federal standards; instead, a defendant may be found liable only in the event (and only to the extent) that the plaintiff can demonstrate noncompliance with those standards. After all, the argument continues, preemption of positive state enactments does not vary depending on each manufacturer's proof of compliance with federal rules.

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[24] *See* Reiter v. Zimmer, Inc., 830 F. Supp. 199, 204 (S.D.N.Y. 1993); Rinehart v. International Playtex, Inc., 688 F. Supp. 475, 477-78 (S.D. Ind. 1988).

[25] *See, e.g.*, Stanton v. Astra Pharmaceutical Prods., Inc., 718 F.2d 553, 565 (3d Cir. 1983); Lowe v. General Motors Corp., 624 F.2d 1373, 1380 (5th Cir. 1980).

[26] *See, e.g.*, Sheridan v. United States, 969 F.2d 72, 75 (4th Cir. 1992); Swift v. United States, 866 F.2d 507, 508-09 (1st Cir. 1989); Eimers v. Honda Motor Co., 785 F. Supp. 1204, 1208 (W.D. Pa. 1992).

[27] *See Cipollone*, 505 U.S. at 528 (1992) (plurality) (noting that the preemption provision would not foreclose recovery on a fraud claim alleging a failure "to disclose material facts about smoking and health to an administrative agency" if state law created a duty to disclose such information); *id.* at 555 (per Scalia, J.) (conceding that "the hypothetical law requiring disclosure to a state regulatory agency would seem to survive" even a sweeping interpretation of the preemption provision). Since the other Justices would have found no claims preempted, *id.* at 543 (per Blackmun, J.), the Court was unanimous in this regard.

Instead, plaintiffs attempting to sustain claims affected by this type of preemption would have to prove any alleged failures to comply with federal requirements. Thus, rather than supporting either an objection to subject matter jurisdiction or a removal petition, preemption in these cases would be regarded as grounds for either a motion for summary judgment or a motion to dismiss for failure to state a claim if plaintiffs have not alleged any failure to comply.

With the proliferation of more or less detailed (and often ambiguous) regulatory requirements, compliance may be difficult to gauge. Questions of compliance with the statutory labeling requirements for cigarettes can be resolved with relative ease, but efforts to determine whether a medical device manufacturer has fully complied with the requirements found in a premarket approval and any generally applicable FDA regulations could present serious difficulties. The matter would, of course, be simplified greatly if an agency successfully had prosecuted the defendant for a regulatory infraction.[28] Although less clearly probative of noncompliance, formal citations alleging a violation also may support a negligence per se claim. At the other extreme, a plaintiff may argue that the defendant has failed to comply with an applicable regulation notwithstanding the agency's apparent acquiescence. In some situations, courts should

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[28] *See, e.g.*, Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 47 (D. Mass. 1994) (noting, however, that some ambiguity remained over the precise infractions to which the manufacturer had pled guilty), *aff'd*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, No. 95-1321 (Feb. 16, 1996).

experience little difficulty resolving such questions, but often the inquiry will be quite complicated.[29/]

Because of such difficulties, courts generally recognize that agencies should exercise primary jurisdiction over regulatory matters within their special expertise.[30/] Indeed, this is one of the premises underlying the strong version of preemption discussed in the previous section. Short of avoiding the compliance issue altogether through complete preemption, however, courts might differentiate between situations where a regulatory infraction is apparent, as when the agency undertakes enforcement action, and other cases where plaintiff has only alleged some failure to comply with an ambiguous requirement. In any case, under the intermediate version of the preemption defense, claims premised on noncompliance would provide plaintiffs with their sole avenue for relief.

C. The Weak Version: Proof of Compliance as a Predicate for the Defense.

Under the weakest version of preemption suggested by courts in the wake of *Cipollone*, defendants would shoulder the burden of proving compliance as a predicate for

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[29/] *See, e.g.*, Lowe v. Sporicidin Int'l, 47 F.3d 124, 130 (4th Cir. 1995); Bammerlin v. Navistar Int'l Transp. Corp., 30 F.3d 898, 900 (7th Cir. 1994); Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990).

[30/] *See, e.g.*, Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 654 (1973).

successfully invoking the preemption defense.[31/] This conception of preemption differs from the intermediate version described in the previous section, which only forecloses recovery on tort claims premised on state law duties **other** than the duty to comply with any applicable federal safety standards. Thus, rather than serving either as a subject matter jurisdiction objection or as grounds for dismissal (or summary judgment) for failure to state a claim, preemption would constitute an affirmative defense.

Because the weak version is poorly elaborated in the reported cases, though perhaps *Cipollone* itself is an example, one must summarize it by comparison to the other conceptions of the preemption defense described previously. If compliance is undisputed, the outcome will be indistinguishable from the result under the other two versions identified above. Under both the strong and intermediate versions, the preemption defense is not dependent on proof of compliance. Courts abiding by the intermediate version recognize negligence per se claims, but there would be no colorable basis for pursuing such claims in the event that compliance is undisputed. Similarly, even if the weak version of the defense is predicated on proof of compliance, a defendant would escape potential tort liability where there is no dispute that it complied with the applicable federal requirements.

In the event of a dispute over compliance, however, the weak version differs from the intermediate version by placing the burden of proof on the defendant. Because the intermediate version of preemption does not make the defense hinge on compliance but only preserves negligence

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[31/] *See, e.g.*, St. Louis S.W. Ry. v. Malone Freight Lines, 39 F.3d 864, 867 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 1963 (1995).

per se claims, plaintiffs would have to carry the frequently difficult burden of establishing noncompliance if they hope to recover damages for their injuries, and even then recovery may be unavailable if a particular jurisdiction does not recognize negligence per se claims for violations of federal standards as a matter of state law.

Under the weak version, by contrast, preemption does not even come into play until the defendant has proven compliance with federal requirements. In light of the potential complexities posed by questions of compliance, this difference in the allocation of the burden may be quite important. Although the plaintiff still shoulders the burden of proof on the underlying tort claims, the defendant's failure to carry the burden with regard to questions of compliance would entirely remove federal preemption from the case (and perhaps invite a negligence per se claim by the plaintiff). Furthermore, under the weak version of preemption, even if the defendant establishes compliance, plaintiffs may be able to rebut that showing by alleging some relevant fraud on the agency.[32]

Finally, if noncompliance is fairly apparent, the weak version may differ from the intermediate version in the sense that the federal safety standards completely drop out of sight even if the defendant's noncompliance is only partial. For example, the failure to abide strictly by the FDA's labeling requirements in a premarket approval may expose the device manufacturer to both failure-to-warn and design defect claims even if there is no evidence that the medical device deviated from design specifications in the product license. Under the

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[32] *See, e.g.*, Hurley v. Lederle Lab., 863 F.2d 1173, 1179-80 (5th Cir. 1988); Butcher v. Robertshaw Controls Co., 550 F. Supp. 692, 694-703 (D. Md. 1981).

intermediate version, by contrast, plaintiffs could pursue only a negligence per se failure-to-warn claim under these circumstances. Second, under the weak version, the defendant's conduct may be judged against a more stringent standard of care in the event of noncompliance, so that even trivial deviations from federal requirements may be regarded as sufficiently extreme departures from the state law standard of reasonable care to support the imposition of punitive damages.[33]

II. PREEMPTION SHOULD BE INTERPRETED AS THE GOVERNMENT STANDARDS DEFENSE.

In the face of such confusion over the proper application of statutory preemption provisions in tort litigation, one might favor the simplicity of a clear statement rule, demanding that Congress specifically enumerate tort claims as preempted before displacing common law remedies.[34] Because the plurality's judgment in *Cipollone* has been fully embraced by the Court, however, a clear statement rule seems unrealistic at this juncture. Alternatively, courts might reconsider implied private rights of action under federal statutes that they have now given sweeping preemp-

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[33] *Cf.* Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 243-44, 258 (1984) (even where violations of federal regulations were at most inconsequential, jury could award punitive damages absent preemption).

[34] *See* Hernandez-Gomez v. Leonardo, 884 P.2d 183, 190 (Ariz. 1994), *vacated sub nom.* Volkswagen of Am., Inc. v. Hernandez-Gomez, 115 S. Ct. 1819 (1995) (remanded for further consideration in light of *Freightliner*); Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1543 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984); *cf.* Atascadero State Hosp. v. Scanlon, 473 U.S. 234, 242 (1985).

tive effect.[35] In a sense, this approach would attempt to fix one arguable error in construing congressional intent--namely, the recent tendency to find express preemption of tort claims notwithstanding congressional silence--with what might well be a second error.[36] Instead, by understanding preemption of tort claims as the government standards defense, the Court could make sense of *Cipollone* without giving it the extreme effect suggested by the strong version of preemption.[37]

Although traditionally compliance with federal safety standards has not protected companies from tort liability, under the strong version of preemption companies are now immunized from liability even if they have violated these standards. Surely this is a remarkable turn of events. Instead, courts should view preemption provisions as nothing more than a decision by Congress to give companies a defense to state tort liability if they have complied with federal safety standards. Of the three different conceptions of preemption that have emerged, *Cipollone* only supports the weak version. Although denoted "preemption," this

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[35] *See, e.g.*, Suter v. Artist M., 112 S. Ct. 1360, 1370 & n.16 (1992); Daily Income Fund, Inc. v. Fox, 464 U.S. 523, 536 (1984); Texas Indus., Inc. v. Radcliff Materials, Inc., 451 U.S. 630, 639 (1981); Cort v. Ash, 422 U.S. 66, 78 (1975).

[36] *See, e.g.*, Mendes v. Medtronic, Inc., 18 F.3d 13, 19 n.4 (1st Cir. 1994); Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); Ginochio v. Surgikos, Inc., 864 F. Supp. 948, 956-57 (N.D. Cal. 1994); Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1022 & n.5 (E.D. Mich. 1993).

[37] For a more detailed treatment of these and other arguments appearing herein, see Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 Wm. & Mary L. Rev. 903 (March 1996).

version of preemption more closely resembles the government standards or approval defense.

Several aspects of *Cipollone* undergird the weak version of preemption. First, the statutory provision at issue in the case made compliance a predicate for invoking the defense.[38] This element of the preemption provision has received little or no attention, however, in part because the tobacco companies have conscientiously used the mandatory warning statements in their labeling. The statutory provision is entitled "Preemption," but, by demanding compliance as a prerequisite for preemption, the cigarette labeling law more closely resembles other federal statutes adopting a government approval defense.[39] Second, because the statute itself specifies the text of these statements, compliance should be relatively simple to determine. Presumably, in the event of noncompliance, a plaintiff alleging injuries from cigarettes would be free to pursue failure-to-warn and related tort claims on theories other than noncompliance with the federal labeling requirement. Arguably, this weak version is not really preemption at all.

Cipollone certainly cannot support the strong version of preemption, in part because of the plurality's distinction between pre- and post-1969 failure-to-warn claims. If the 1969 amendments were understood as completely preempting failure-to-warn claims, then the provision would foreclose

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[38] *See* 15 U.S.C. § 1334(b) (1994) (preempting the imposition of requirements or prohibitions under state law with respect to cigarettes "labeled in conformity with the provisions of this Act").

[39] For example, the National Childhood Vaccine Injury Act provides a compliance defense against failure-to-warn and manufacturing defect claims. *See* 42 U.S.C. §§ 300aa-22(b), 300aa-23(d) (West Supp. 1995).

any tort actions founded on such claims that are brought after 1969, whether or not some of the defendant's alleged negligence pre-dated enactment of the statute.[40] Instead, of course, the *Cipollone* plurality distinguished between claims grounded on *conduct* occurring before and after passage of the preemption provision. Finally, by differentiating among numerous tort claims and only finding preemption of a limited class that was based on a failure to warn, the plurality's decision in *Cipollone* left a number of alternative grounds for recovery available to plaintiffs, so the practical result of preemption was not particularly harsh in that case.

Although preemption provisions in the MDA and other statutes are broader than that applicable to cigarettes, it is not clear that *Cipollone* really dictates the recognition of more sweeping preemption defenses in those cases. None of the other statutes include a similar compliance prerequisite in the text of the preemption provision, and compliance with requirements imposed under those statutes is also harder to determine, but these are reasons for narrowing or distinguishing *Cipollone* rather than unthinkingly giving it even greater effect in other contexts. In particular, the absence of substitute remedies should incline courts against finding preemption of tort law claims unless congressional intent to foreclose such claims is unmistakable.[41] Interpreting preemption provisions as establishing a government standards defense would promote the goal of federal uniformity without foreclosing common law remedies where federal safety standards have been violated.

In a sense, the Court would be recognizing a federal common law defense against state tort claims when a product or activity is subject to regulation under a federal statute that contains a preemption provision. The Court recognized an analogous defense against products liability claims for government contractors supplying military equipment. Like the weak version of preemption, a contractor first would have to identify the government requirements that trigger the defense, then demonstrate compliance with those specifications, and finally not be guilty of fraud or misrepresentation in its dealings with the government.[42] The case for recognizing a government standards defense for compliance with certain federal safety requirements is even stronger than for the contractor defense because the Court can interpret the express preemption provisions in the relevant statutes as more directly justifying the recognition of such a defense as a matter of federal common law. Although the development of federal common law rules generally is reserved for extraordinary circumstances, such interstitial lawmaking is preferable to the tortured feats of statutory construction

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[40] Although retroactive application of statutes generally is disfavored, see Landgraf v. USI Film Products, 114 S. Ct. 1483, 1496-1504 (1994), complete preemption (operating as a jurisdictional rule, *id.* at 1501-02) would foreclose any claims filed after enactment even if premised on conduct pre-dating the statute. *See, e.g.*, Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 959 F.2d 158, 160-61 (10th Cir.) (holding that FIFRA preempted failure-to-warn claims even though defendant's allegedly negligent conduct entirely pre-dated enactment of the preemption provision), *vacated*, 113 S. Ct. 314 (1992), *reinstated*, 981 F.2d 1177, 1178 (10th Cir.), *cert. denied*, 114 S. Ct. 60 (1993).

[41] *See, e.g.*, Hodges v. Delta Airlines, Inc., 44 F.3d 334, 338 & n.8 (5th Cir. 1995) (en banc); Abbot v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1440 (C.D. Cal. 1994). Of course, the plurality in *Cipollone* and the majority in *Easterwood* did not construe the respective statutes so narrowly, but then only the weaker versions of preemption discussed above seem appropriate.

[42] Boyle v. United Technologies Corp., 487 U.S. 500, 512 (1988).

engaged in when lower courts find sweeping express preemption of tort claims.

The theoretical difference between interpreting such provisions as dictating preemption of tort claims or as authorizing courts to fashion a government standards defense may be inconsequential. Even so, courts could decide that a provision preempting state law demonstrates a sufficiently strong interest in uniformity (but not exclusivity) to support application of the government standards defense against tort claims. Whether the defense recognized in *Cipollone* is styled as preemption or government standards, however, this Court should more clearly articulate the prerequisites for invocation of the defense. The three-part government contractor defense suggests one useful formulation that could be readily adapted to this end.

To be sure, significant controversy surrounds the use of the government standards defense. Several justifications are offered in support of its recognition. For instance, allowing recovery of tort damages notwithstanding conscientious adherence to carefully crafted safety standards is both inefficient and unfair, and lay jurors are not qualified to second-guess the safety determinations made by federal regulators. Proponents also argue that the traditional assumptions underlying the hesitancy to accept a government standards defense are open to serious question in light of the radical changes in the regulatory state. The relative strength of these arguments may well vary across different product categories.

Conversely, critics make a number of cogent arguments against the recognition of such a defense to liability. For example, the tort system has the virtue of encouraging product manufacturers to discover and address health and

safety risks before they result in serious injuries, whereas regulators generally can react only after such injuries have come to light. Opponents of the defense also express little or no faith in the reliability of administrative agencies, and they note that government standards may be quite difficult to discern and apply. Finally, of course, the federal government generally offers no direct system of compensation for persons who are injured.

Nonetheless, even critics of the defense should agree that a government standards interpretation of express preemption provisions is far better than the stronger versions of preemption that have been adopted by a number of courts. Furthermore, by deciding that preemption translates into the government standards defense when raised in the context of tort litigation, the Court could decouple the defense and arguments about its desirability from the conceptually different issue of federal preemption of positive state enactments.

* * * * *

Cipollone was decided under the rubric of federal preemption. Perhaps this was an unfortunate choice of terminology by Congress because it has caused great mischief in other contexts. Before 1992, the Court did not accept preemption as a defense to tort liability, at least not unless the statute provided a substitute remedy or otherwise granted exclusive jurisdiction to a federal agency. The plurality's judgment in *Cipollone*, as refined in a pair of subsequent decisions by this Court, signalled a new willingness to accept preemption as a defense to tort claims.

A number of lower courts have read *Cipollone* and its progeny as an invitation to cut off plaintiffs' access to tort

remedies, even in extreme situations where a company has not complied with the federal requirements that are being given preemptive effect. This strong version of preemption represents the least defensible reading of *Cipollone*. The intermediate version, which does not preempt claims if they are premised on violations of federal requirements, is somewhat more sensible but arguably still more protective than *Cipollone* demands (for instance, where negligence per se claims are not available under state law). Instead, the weak version of preemption, which is really indistinguishable from the government standards defense, is more in keeping with what the Court actually decided in that case. Under this approach, proof of compliance is a predicate for invoking this affirmative defense, and evidence of fraud on the responsible agency could defeat it.

CONCLUSION

For the foregoing reasons, *amici* urge this Court to clarify, in the course of resolving the instant petitions, the limited nature of the preemption defense to tort claims.

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

MEDTRONIC, INC.

Petitioner and Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR

Respondents and Cross-Petitioners.

On Writ of Certiorari to
the United States Court of Appeals
for the Eleventh Circuit

BRIEF *AMICUS CURIAE* OF TRIAL LAWYERS FOR PUBLIC JUSTICE, P.C., IN SUPPORT OF LORA LOHR AND MICHAEL LOHR

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36 pp

TABLE OF CONTENTS

INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

ARGUMENT 5

I. LOWER COURTS HAVE EXTENDED THE PREEMPTIVE EFFECT OF THE MDA FAR BEYOND ITS PROPER SCOPE 5

II. THE MDA DOES NOT EXPRESSLY PREEMPT STATE-LAW CLAIMS FOR DAMAGES 12

A. TORT LAW, UNLIKE REGULATORY STATUTES, PRIMARILY FOCUSES ON COMPENSATING INJURED VICTIMS 15

B. THE COMPENSATORY GOALS OF TORT LAW COMPLEMENT RATHER THAN CONFLICT WITH THE REGULATORY GOALS OF FEDERAL CONSUMER PROTECTION STATUTES 19

C. REGULATORY AGENCIES LIKE THE FDA DO NOT ADDRESS MATTERS OF COMPENSATION 20

D. MEDTRONIC'S ARGUMENTS ARE UNAVAILING 21

III. THIS COURT SHOULD CLARIFY THE LIMITED SCOPE OF PREEMPTION DOCTRINE 26

CONCLUSION 29

TABLE OF AUTHORITIES

Cases: **Page**

Bank One Chicago, N.A. v. Midwest Bank & Trust Co., 116 S. Ct. 637 (1996) 6
Bennis v. Michigan, No. 94-8729, 1996 U.S. Lexis 1565 (Mar. 4, 1996) 15
Brown v. Hotel Employees, 468 U.S. 491 (1984) 18
Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989) 10
Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) 6
Cipollone v. Liggett Group, Inc., 789 F.2d 181 (3d Cir. 1986), *rev'd in part and aff'd in part*, 505 U.S. 504 (1992) 2, 9
Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 4, 9, 11, 12, 22, 24, 26
Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995) 11
Edwards v. Murray Chris-Craft Sportboats, Inc., 873 F. Supp. 618 (M.D. Fla. 1994) 27
English v. General Electric Co., 496 U.S. 72 (1990) 4, 17, 18
Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469 (1992) 13
Freightliner Corp. v. Myrick, 115 S. Ct. 1483 (1995) . . . 28
Gade v. National Solid Wastes Management Ass'n, 505 U.S. 88 (1992) 18
Goodyear Atomic Corp. v. Miller, 486 U.S. 174 (1988) . 17
Gregory v. Ashcroft, 501 U.S. 452 (1991) 27
Heck v. Humphrey, 114 S. Ct. 2364 (1994) 15
Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) 23
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Lindquist v. Tambrands, Inc., 721 F. Supp. 1058 (D. Minn. 1989) 9
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Nevada v. Hall, 440 U.S. 410 (1979) 27
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Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993) 11
Stephen v. American Brands, Inc., 825 F.2d 312 (11th Cir. 1987) 9
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Tetuan v. A.H. Robins Co., 738 P.2d 1210 (Kan. 1987) . 10
Toibb v. Radloff, 501 U.S. 157 (1991) 6
United Construction Workers v. Laburnum Construction Corp., 347 U.S. 656 (1954) 16
U.S. Term Limits, Inc. v. Thornton, 115 S. Ct. 1842 (1995) 28
Vaca v. Sipes, 386 U.S. 171 (1967) 18
Welchert v. American Cyanamid, Inc., 59 F.3d 69 (8th Cir. 1995) 27
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Pub. L. No. 101-629, 104 Stat. 4511 7
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21 U.S.C. § 360h(d) 12
21 U.S.C. § 360i(b) 7
21 U.S.C. § 360(k) 11, 23
21 U.S.C. § 360k(a) 2, 6, 12-14, 23
141 Cong. Rec. S6453 (May 10, 1995) 8
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N.J. Stat. Ann. § 2A:58C-5(c) 26
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Ohio Rev. Code Ann. § 2307.80(C) 26
Or. Rev. Stat. § 30.927 26
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Utah Code Ann. § 78-18-1 26

Regulations and Administrative Materials:

21 C.F.R. § 10.85(e) 7
21 C.F.R. § 801.430(c) 10-11
21 C.F.R. § 801.430(d) 10
21 C.F.R. § 807.97 23
21 C.F.R. § 808(d)(1) 6

Miscellaneous: **Page**

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Nos. 95-754, 95-886

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1995

MEDTRONIC, INC.

Petitioner and Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR

Respondents and Cross-Petitioners.

BRIEF *AMICUS CURIAE* OF TRIAL LAWYERS FOR PUBLIC JUSTICE, P.C., IN SUPPORT OF LORA LOHR AND MICHAEL LOHR

INTEREST OF *AMICUS CURIAE*

With the consent of the parties, as reflected in letters filed with the Clerk pursuant to Rule 37.3(a), *amicus curiae* Trial Lawyers for Public Justice, P.C. ("TLPJ"), hereby submits this brief in support of cross-petitioners/respondents Lora Lohr and Michael Lohr.

TLPJ is a national public interest law firm devoted to representing people injured by corporate or government illegality. TLPJ is supported by and utilizes the services of more than 1,500 trial lawyers throughout the United States and has represented many plaintiffs in cases against manufacturers of dangerous products. TLPJ is the only public interest firm in the nation dedicated to the preservation of the States' individual tort systems as the surest, and often sole, means of compensation to people injured by defective products.

Accordingly, TLPJ has often participated, as primary or

amicus counsel, in state and federal trial and appellate cases in which the preemption doctrine was a pivotal issue. As in those cases, the manufacturer of the dangerous product in this action seeks to thwart the proper functioning of the tort system through the misapplication of preemption doctrine.

SUMMARY OF ARGUMENT

I. For a decade after the adoption of the Medical Device Amendments (MDA) in 1976, medical device manufacturers did not even argue that the statute preempted state common-law damages claims. Their failure to raise preemption defenses is entirely understandable, for the text of the MDA does not expressly refer to the preemption of common-law claims; the legislative history is similarly silent on the subject; the FDA, which administers the statute, has construed it as *not* preempting state-law claims for damages; and Congress itself — by continuing to consider proposals to confer tort immunity on manufacturers that comply with the MDA — has indicated its understanding that it does not share Medtronic's view of the statute.

Tellingly, manufacturers began to raise preemption as a defense in medical device litigation not after any statutory change, or new disclosures about Congress' intent — for there were none — but rather after the since-rejected decision of the U.S. Court of Appeals for the Third Circuit in *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986), *rev'd in part and aff'd in part*, 505 U.S. 504 (1992), which unduly expanded the preemptive reach of the federal cigarette warning-label statutes. This Court corrected the Third Circuit's erroneous reasoning, but not before it infected construction of the MDA. As a result, many lower courts are now finding state common-law claims *expressly* preempted when those present at the MDA's enactment properly understood that such claims were not preempted at all.

II. This Court should make clear that the MDA does not expressly preempt state common-law damages claims. The reference to state-law "requirement[s]" in 21 U.S.C. § 360k(a)

pertains to positive-law enactments, not tort suits.

Medtronic has attempted to reduce the questions presented in this case to the following dichotomy:

> Did Congress, recognizing the dangers of over-regulation by the states, leave design issues to federal experts, who may authorize or proscribe the marketing of particular designs and employ a variety of remedial tools to cope with any problems discovered after marketing begins? Conversely, did Congress fear under-regulation at the federal level, leaving in place tort claims that allow juries and judges in fifty states to determine, after the fact, whether a particular design authorized for marketing by the federal experts falls beneath a state law standard of care?

Br. for Pet. Medtronic, Inc. at 2.

The dichotomy posited by Medtronic is a false one. There is no reason to think that Congress conceived of state common law as competing with a system of federal regulation. Positive-law enactments such as statutes, ordinances, and regulations address future conduct. Such enactments are backed by the coercive force of government and leave no room for choice. Tort law, by contrast, looks backward: despite its secondary deterrence function, tort law's primary goal is to compensate victims of past conduct. *E.g.*, William Prosser and Page Keeton, PROSSER & KEETON ON TORTS § 1 at 5, 7 (1984) ("[Tort law] is directed toward the compensation of individuals . . . . its primary purpose is to compensate for the damage suffered, at the expense of the wrongdoer."). Moreover, an tort action for damages does not "require" a defendant to change its conduct in the future, because it leaves the defendant free to pay damages and continue its conduct unaltered.

There is no inherent conflict between the regulatory goals of federal statutes and the principally compensatory goals of state tort law. In fact, the principally compensatory goals served by tort law are completely different from the regulatory goals served by statutes.

Accordingly, absent an explicit statement of congressional

intent to the contrary, this Court should recognize, as a presumptive matter, that Congress does not intend to displace the compensatory element of state tort law. This presumption should be particularly compelling where Congress has not itself provided a parallel mechanism for compensation, for it is difficult to believe that Congress would leave injured persons without a remedy. *See English v. General Electric Co.*, 496 U.S. 72, 85 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Moreover, there are powerful reasons to think that Congress did not intend the kind of immunity sought by Medtronic. Such an immunity would weaken manufacturers' incentive to develop safer products and would eliminate the important information-gathering function of the tort system. Furthermore, matters of compensation are not within the expertise or jurisdiction of regulatory agencies like the FDA. To hold that regulatory acquiescence supersedes all tort liability supposes that Congress intended to centralize all authority in the FDA for judging not only scientific issues but also for balancing the interests of injured consumers. Congress plainly did not design such a system.

Medtronic's reliance on *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), is entirely misplaced. In that case, this Court recognized that "there is no general, inherent conflict" between regulation and state common law damages actions. *Id.* at 518. Indeed, the holding of the majority opinion in *Cipollone* was that a 1965 statute providing that "[n]o statement relating to smoking and health shall be *required* in the advertising of [properly labeled] cigarettes" did not extend to common-law claims for damages.

Medtronic instead relies on the decision of the *Cipollone* plurality that tort claimants could not bring common-law claims challenging the effectiveness of congressionally drafted and mandated cigarette warnings under the 1969 statute. But this reasoning confirms that the MDA does not preempt common-law claims, because — in contrast to the 1969 cigarette statute — the MDA leaves ample room for manufacturer choice in designing, manufacturing, packaging, and labeling medical devices.

III. This case presents this Court with the opportunity to clarify several important principles of preemption law: (1) that there is no inherent conflict between federal consumer protection statutes and state tort law because the former are concerned principally with prospectively regulating harmful behavior, while the latter is tied primarily to the goal of compensation; (2) that express preemption analysis must be confined to a close textual inquiry that honors rather than disregards congressional intent; and (3) that implied preemption inquiries must similarly be limited, particularly where Congress has addressed the matter of preemption in the statute.

Common-law tort actions and state positive-law enactments should not readily be equated. Preemption analysis must proceed with the recognition that, when Congress decides to oust state law, particularly law that has been venerated for centuries, it does so with great care and precision — with a scalpel, not a meat axe.

ARGUMENT

There is an urgent need for this Court to clarify preemption doctrine in order to curtail what have become essentially freewheeling judicial exercises showing little regard for the handiwork of Congress or the constitutional interests of federalism. The treatment of the MDA in the lower courts exemplifies the danger of this trend.

I. LOWER COURTS HAVE EXTENDED THE PREEMPTIVE EFFECT OF THE MDA FAR BEYOND ITS PROPER SCOPE

1. The MDA was adopted in 1976. For more than a decade afterward, no medical device manufacturer even raised preemption as a defense to a damages claim, according to the reported cases.[1] The reasons are not hard to fathom:

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[1] In *National Women's Health Network v. A.H. Robins*, 545 F. Supp. 1177,

• The text of the MDA contains no express reference to preempting state-law damages claims.[2]

• "A careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 923 n.128 (1994). Quite apart from the traditional rule that "a court appropriately may refer to a statute's legislative history to resolve statutory ambiguity,"[3] recourse to legislative history is useful because a striking omission from the legislative record — like the dog that did not bark — can itself be telling evidence. *See New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1681 (1995) (refusing to find preemption because "there is not so much as a hint in [the statute's] legislative history or anywhere else that Congress intended to squelch these state efforts").

• The FDA, whose views are entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), recognized that the MDA does not preempt "State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes and the Uniform Commercial Code (warranty of fitness)) or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808(d)(1). If the MDA does not preempt general bodies of *positive law*,

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1181 (D. Mass. 1982), the defendant argued that the MDA preempted any state court authority to order a worldwide notification and recall campaign for the Dalkon Shield, but tellingly did not raise a preemption defense with respect to the plaintiffs' claims for damages.

[2] We discusss 21 U.S.C. § 360k(a) in Part II, *infra*.

[3] *Toibb v. Radloff*, 501 U.S. 157, 162 (1991); *see also Bank One Chicago, N.A. v. Midwest Bank & Trust Co.*, 116 S. Ct. 637, 644 (1996) (Stevens, J., concurring); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 610 (1991); Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 860-61 (1992).

such as the UCC, then *a fortiori* it does not preempt generally applicable bodies of state tort law. Thus, the FDA has issued an advisory opinion — which is binding on the agency pursuant to 21 C.F.R. § 10.85(e) — outlining the Commission's view that the MDA does not displace common-law claims.[4]

• Since adopting the MDA, Congress has repeatedly evinced its understanding that the statute does not displace common-law claims. For example, when it amended the MDA in 1990, *see* Pub. L. No. 101-629, 104 Stat. 4511, Congress provided that a medical device "user facility," whenever it becomes aware that a medical device has caused a serious injury or death, must submit a "user report" of the death or injury to the Secretary of Health and Human Services. 21 U.S.C. § 360i(b). The accompanying legislative history expresses Congress' understanding that patients injured by medical devices would have the right to sue the manufacturer.[5] Indeed, over the past two decades, Congress has considered numerous proposals to bar tort claims against medical devices that have received FDA premarket approval — proposals which would have been wholly unnecessary if Medtronic's view of the statute were correct.[6]

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[4] *See* Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to Robert E. Manchester, National Women's Health Network (Mar. 8, 1984), reprinted at Pet. App. 4a-6a in *Lohr v. Medronic, Inc.*, No. 95-886.

[5] *See* H.R. Rep. No. 808, 101st Cong., 1st Sess. 21 (1990) ("The FDA is prohibited from disclosing the identity of medical device user facilities that file reports, except in very limited circumstances. The reports may not be admitted into evidence or otherwise used in any civil actions involving private parties. *However, there is no prohibition on civil litigation about the events that are the subject of the report.*") (emphasis added).

[6] *E.g., Hearings on S. 1400, the Product Liability Reform Act, Before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation*, 101st Cong., 2d. Sess. 1 (1990) (statement by Sen. Bryan that Congress has been grappling with "controversial" product liability issues "for a good many years"); *id.* at 5 (statement by Sen. Gorton that the issue of product liability "is not new. . . . The debate heats up when the different factions — business, consumer groups, lawyers — attempt to

Not surprisingly, therefore, for at least ten years after the MDA's adoption, the "prevailing view" was that "a manufacturer's failure to comply with an FDA standard generally triggered a finding in court of negligence *per se* against the manufacturer, but the manufacturer's compliance with an FDA standard provided little protection against tort claims of a plaintiff." Adler & Mann, *supra*, 59 MO. L. REV. at 916.[7]

For example, in *Wooderson v. Ortho Pharmaceutical, Inc.*, 681 P.2d 1038, 1055, 1057 (Kan.), *cert. denied*, 469 U.S. 965 (1984), the Kansas Supreme Court upheld an award of punitive damages against a manufacturer despite its compliance with FDA-approved labelling. Similarly, in *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988), the Tenth Circuit affirmed a multimillion-dollar judgment against a tampon manufacturer in a toxic shock syndrome case. Rather than framing an explicit preemption defense, the manufacturer contended merely "that its compliance

craft a solution"); *id.* at 315 (statement by Sen. Kasten that bills had been modified to eliminate "[c]ompliance with [FDA] standards defenses for compensatory damages . . ., an issue that we have discussed which was contentious").

Because such proposals have proved extremely controversial, in recent years proponents have scaled back the proposed immunity to bar the imposition of only *punitive* damages against products that comply with FDA requirements. *E.g.*, 141 Cong. Rec. S6453 (May 10, 1995) (statement of Sen. Dodd) (discussing provision of S. 565, the Product Liability Fairness Act of 1995, creating exemption from punitive damages for compliance with FDA standards). Even these more modest provisions have failed to pass Congress. Hence, according broad preemptive effect to the MDA would by judicial fiat grant medical device manufacturers a far greater immunity than they have ever been able to secure through the legislative process.

[7] *E.g.*, Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 243 (Winter 1987) ("Under current law, compliance with the FDA's requirements affords only modest protection against the successful lawsuit."); Frederick H. Fern, *FDA Standards Are Not the Final Word*, 14 THE BRIEF 24 (Spring 1985) (discussing imposition of punitive damages despite compliance with FDA requirements).

with FDA standards entitled it to judgment as a matter of law." *Id.* at 1443. The court of appeals dismissed that argument.

2. Manufacturers began to assert preemption defenses in medical device cases not after any revelation about the statute or Congress' intent, but after the since-rejected decision of the Third Circuit in *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986), *rev'd in part and aff'd in part*, 505 U.S. 504 (1992), regarding the federal cigarette warning-label statutes. The Third Circuit held state tort actions preempted, on the ground that they would upset Congress' "carefully drawn balance between the purposes of warning the public of the hazards of cigarette smoking and protecting the interests of the national economy." 789 F.2d at 187.[8]

Before this Court had the opportunity to repudiate the Third Circuit's reasoning by limiting use of implied preemption analysis and by reaffirming that "there is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law damages actions," 505 U.S. at 518, the Third Circuit's faulty strain of preemption analysis in *Cipollone* had infected the interpretation of the MDA. Relying explicitly on the cigarette cases, lower courts began to find that a special FDA-prescribed warning label for tampons preempted claims challenging the efficacy of that warning. *See, e.g., Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1063 (D. Minn. 1989) ("[T]he medical device cases are very similar to the cigarette cases. . . . From [Congress'] carefully wrought balance is inferred a legislative intent to preempt state law warning claims."); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 477 (S.D. Ind. 1988) (relying on *Palmer v. Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987)).

[8] Within a year, the First and Eleventh Circuits issued similar decisions. *Palmer v. Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987); *Stephen v. American Brands, Inc.*, 825 F.2d 312 (11th Cir. 1987).

Not all courts made this mistake,[9] and even the courts finding failure-to-warn claims preempted recognized that state-law claims based on the design, composition, and construction of tampons were not displaced.[10] Moreover, the tampon labeling cases were distinguished by an unusual feature: the FDA had mandated a special consumer warning label,[11] an approach the FDA has

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[9] *E.g.*, *Kerns v. International Playtex, Inc.*, No. C-1-86-297 (S.D. Ohio Apr. 15, 1988); *Muzatko v. International Playtex, Inc.*, No. 85-C-1540 (E.D. Wis. May 14, 1987); *Peters v. J&J Products, Inc.*, No. 842-00765 (Mo. Cir. Ct. May 3, 1988). Other lower courts rejected preemption defenses in early IUD cases. *E.g.*, *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 664 (D. Md. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1299 (D. Minn. 1988); *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1232-33 (Kan. 1987).

[10] *E.g.*, *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 (5th Cir. 1989); *Rhinehart*, 688 F. Supp. at 477-78.

[11] In 1982, in response to a discovered association between toxic shock syndrome ("TSS") and tampons, the FDA adopted special labeling regulations for tampons mandating that the following consumer information appear "prominently and legibly in a package insert or on the package in terms understandable by the layerson[:]"

(1) the warning signs of TSS and what to do if the warning signs appear;

(2) the statistical risk of TSS to women using tampons;

(3) the advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) the potential for avoiding the risk of getting tampon-associated TSS by not using tampons and the potential for "possibly reducing" the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods;

(5) the need to seek medical attention "before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use."

21 C.F.R. § 801.430(d). If the above information was provided in a package insert, then the following "alert statement" was required to appear "prominently and legibly" on the package label:

ATTENTION: Tampons are associated with Toxic Shock

taken only for tampons, hearing aids, and a handful of other products. There is nothing comparable to this specific FDA action in this case.

3. Nonetheless, the stage was set for further defective preemption analysis. After this Court curtailed implied preemption analysis in *Cipollone*, lower courts began explicitly to equate positive-law enactments (like state regulations and statutes) with common-law actions and to hold that the MDA *expressly* preempted state-law claims for damages,[12] both in the context of premarket approvals (PMAs) issued by the FDA under 21 U.S.C. § 360e(c)(1), and in the context of the much less rigorous "substantial equivalence" standard of § 510(k). *See id.* at §§ 360e(b)(1)(B), 360c(f)(1)(A).[13]

Thus, lower courts are now finding as *expressly* preempted state-law claims that those present at the MDA's enactment understood were not preempted at all. It is highly implausible, to say the least, that a statute long accepted as having no preemptive effect on common-law claims can be said to contain a "clear and manifest" congressional statement to displace those claims in the wholesale fashion that Medtronic seeks. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

21 C.F.R. § 801.430(c).

[12] *See, e.g.*, *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 505 U.S. 917 (1992); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

[13] *See, e.g.*, *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 399-400 (4th Cir. 1995).

II. THE MDA DOES NOT EXPRESSLY PREEMPT STATE-LAW CLAIMS FOR DAMAGES

The MDA does not expressly refer to state-law damages claims, except insofar as it provides that compliance with FDA recall and similar orders *does not* relieve manufacturers from liability in damages actions. 21 U.S.C. § 360h(d). The provision cited by Medtronic provides that (1) "no State or political subdivision of a State" may (2) "establish or continue in effect" (3) "any requirement" (4) "with respect to a device" that (5) is "different from, or in addition to, any requirement applicable under this chapter to the device," and "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

This statutory language does *not* expressly displace any state common-law claims for damages:

(1) The phrase "State or political subdivision of a State" reflects that Congress was referring to positive state law, not to common-law claims. This is not a phrase that Congress would have used to refer to the bodies that issue or apply the common law. Although the term "state law" may include common law as well as statutes and regulations, *Cipollone*, 505 U.S. at 522 (plurality opinion), neither a court nor a jury in a state court case (much less a jury in a federal court case applying state law) is typically referred to as a "State or political subdivision of a State." By comparison, when legislation is signed into law, when regulations are promulgated, or when ordinances are adopted, it is often said that "a State" (or a county or city) has changed its law. That terminology simply is not used when a jury applies the common law to the facts of a particular case.

(2) States do not "establish or continue in effect" requirements by means of the common-law tort system. The general norms embodied in the common law have been "established" over hundreds of years. Nor do individual verdicts "continue in effect" any form of requirements. Indeed, because compensation, rather than injury prevention, is the primary purpose of tort law, tort actions are not ordinarily structured to

provide specific guidance to manufacturers on precisely how to alter their conduct. A manufacturer is simply found negligent or otherwise liable.

(3) The word "requirement," read in context, plainly refers to positive enactments, not common law claims. The word is used three times in § 360k(a). In two instances,[14] it unquestionably means positive enactments, not court actions for damages. Only once, in the reference to state-law requirements, is the word even arguably ambiguous. It is "a basic canon of statutory construction that identical terms within an Act bear the same meaning." *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992).

(4) Common-law claims do not establish or continue requirements "with respect to a device" at all, because a defendant is always free — indeed, sometimes is expected — to pay damages rather than to modify its conduct. The only action ever *required* by a tort claim is the payment of a damages judgment — not action *with respect to a device*. Thus, a defendant is always able to comply with the federal requirement *and* to pay compensation to those injured by its misconduct. There is no possibility of incompatible legal commands in ordinary damages suits, and Medtronic's footnoted claim to the contrary is simply inaccurate. Br. of Pet. Medtronic at 46 n.24.[15]

Moreover, common-law claims do not impose requirements "with respect to a device," because they draw upon generally applicable norms — the duty not to deceive, the duty to behave non-negligently — that were not developed with reference to medical devices and that may be applied differently by different

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[14] 21 U.S.C. § 360k(a)(1) ("any *requirement* applicable under this Act"); *id.* at § 360k(a)(2) ("a *requirement* applicable to the device under this Act").

[15] There is no "actual conflict" or physical "impossib[ility]," Br. of Pet. Medtronic, Inc. at 46 n.24, between federal regulation of health and safety risks and state tort liability with respect to injuries that regulation has not prevented. The experience with FDA-approved drugs demonstrates that there is no such incompatibility.

factfinders in different cases.

(5) For the same reason, common-law claims do not establish or continue any requirement with respect to the device that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" or that "relates to the safety or effectiveness of the device." Common-law claims focus primarily on compensating injured persons, not on prospectively deterring harmful conduct. As this Court has recognized — unanimously — the concept of "relating to" cannot be "taken to the furthest stretch of its indeterminacy," in the preemption context. *New York Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995). If it were, "then for all practical purposes pre-emption would never run its course, for '[r]eally, universally, relations stop nowhere.' But that, of course, would be to read Congress's words of limitation as mere sham, and to read the presumption against pre-emption out of the law whenever Congress speaks to the matter with generality." *Id.* (citation omitted).

The rule that § 360k(a) does not preempt common law claims is neither unworkable nor threatening to the ability of medical device manufacturers to do business. It merely applies in the field of medical devices the same relationship between regulation and tort liability that exists under the statute to which the MDA was an amendment — the Food, Drug, and Cosmetic Act of 1938 (FDCA), a statute that has always been construed as permitting consumers to bring state-law damages claims for injuries caused by unsafe drugs, foods, or cosmetics. *E.g.*, *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 811 (1986) (suit against drug manufacturer arises under state rather than federal law and "is a subject traditionally relegated to state law").

The text, structure, and legislative history of the MDA reveal not even a hint of congressional intent to place devices in such a drastically different position from other products regulated under the FDCA. There is no logical reason to think that Congress would have wanted to do so. In fact, longstanding legal principles that form the background understanding against which Congress legislated make it impossible to ascribe the broad

preemptive effect to the MDA that Medtronic seeks.

A. TORT LAW, UNLIKE REGULATORY STATUTES, PRIMARILY FOCUSES ON COMPENSATING INJURED VICTIMS

Medtronic contends that, in passing the MDA, Congress "had to choose" into which of two categories state common-law actions fell: "a useful supplement to [Congress'] own safeguards against unsafe and ineffective devices" or "an unnecessary restriction that might impede its goal of promoting device innovation and availability." Br. of Pet. Medtronic, Inc. at 4. Medtronic ignores a third (and the most obvious) possibility: that Congress treated common-law damages actions as having little to do with its regulatory system because they serve primarily compensatory goals that are entirely separate from the matters addressed by the MDA.

1. Although tort law has incidental deterrent effects, its principal purpose is to compensate injured victims.[16] "'Over the centuries the common law of torts has developed a set of rules to implement the principle that a person should be compensated fairly for injuries caused by the violation of his legal rights.'" *Heck v. Humphrey*, 114 S. Ct. 2364, 2370 (1994) (citation omitted). The tort system operates on a retrospective basis. Each case requires an examination of the particular facts regarding a particular victim and a particular tortfeasor. "Tort law is tied to the goal of compensation . . . ." *Bennis v. Michigan*, No. 94-8729, 1996 U.S. Lexis 1565, * 47 n.13 (Mar. 4, 1996) (Stevens, J., dissenting); *see also Simon & Schuster, Inc. v. New York Crime Victims Bd.*, 502 U.S. 105, 118 (1991)

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[16] *See, e.g.*, Stephen Breyer, REGULATION AND ITS REFORM 176 (1982) (explaining that tort law has deterrent effects, but that "the common law, as administered by the courts, may reflect certain noneconomic or moral factors that will make it difficult to use shifts in common-law liability to achieve basically economic ends").

("Every State has a body of tort law serving" its "compelling interest" in "ensuring that victims . . . are compensated by those who harm them.").

By contrast, statutes and regulations are typically prospective in nature and focus not on compensating persons for injuries already sustained but on preventing socially harmful activities. "Regulation is not designed to provide or account for compensation" to the victims of dangerous products and their families. Mary Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 172 (1995). Safety standards can only attempt to head off similar deaths or serious injuries in the future.

2. The difference between the tort and regulatory systems means that a congressional decision to prevent States from adopting conflicting positive-law enactments is entirely different from a decision to curtail the compensatory function of tort law. Even if a State cannot alter a product's design, it should be able to provide a judicial system that resolves claims for wrongful injuries to its citizens and decides that, as between a manufacturer and an injured party, the manufacturer ought to bear the cost of compensating for those injuries that it could have prevented. To hold otherwise conflates the distinct elements of the tort system: its primary function in providing compensation and its secondary function in supplementing the deterrent effect of regulations.

Recognizing the important distinction between regulation and the tort system, this Court has traditionally held that statutes like the MDA do not cut off victims' rights to fair compensation under state law. In *United Construction Workers v. Laburnum Construction Corp.*, 347 U.S. 656 (1954), for example, this Court observed:

> Congress has neither provided nor suggested any substitute for the traditional state court procedure for collecting damages for injuries caused by tortious conduct. For us to cut off the injured respondent from this right to recovery will deprive it of its property without recourse or compensation. To do so will, in effect, grant petitioners

> immunity from liability or their tortious conduct. We see no substantial reason for reaching such a result.

Id. at 663-64.

In *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), this Court held that the comprehensive scheme of federal regulation of nuclear energy facilities pursuant to the Atomic Energy Act of 1954 did not preempt a state-law claim for punitive damages arising from conduct relating to radiation hazards. This Court reasoned that:

> there is no indication that Congress even seriously considered precluding the use of such remedies either when it enacted the Atomic Energy Act in 1954 and or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. *It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.*

Id. at 251 (emphasis added). Accordingly, this Court determined that "Congress assumed that such [state-law] remedies would be available." *Id.*

Similarly, in *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174 (1988), this Court distinguished, for purposes of preemption analysis, "direct state regulation" of safety matters from "the incidental regulatory effects" of damages awarded pursuant to a state workers' compensation law. *Id.* at 185. In *English v. General Electric Co.*, 496 U.S. 72 (1990), this Court held that state common-law damages claims for emotional distress were not preempted by federal nuclear energy law. The Court concluded that, although awards to former employees for emotional distress would attach "additional consequences" to retaliatory employer conduct and could lead employers to alter the underlying conditions that were the subject of employee complaints, such effects would be "neither direct nor substantial enough" to warrant preemption. *Id.* at 85.

To be sure, common-law claims can have an incidental

regulatory effect on a defendant's conduct. But the principal function of the tort system is compensatory. And many state laws have indirect "regulatory effects" on tortfeasors' conduct, yet this Court has ordinarily held them not preempted in the absence of a very explicit congressional statement that they be displaced. *E.g.*, *New York State Conf. of Blue Cross & Blue Shield Plans*, 115 S. Ct. at 1683 (ERISA does not preempt state surcharges on hospital patients covered by commercial insurance because "they affect only indirectly the relative prices of insurance policies, a result no different from myriad state laws in areas traditionally subject to local regulation, which Congress could not possibly have intended to eliminate."); *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 107 (1992) (federal Occupational Safety and Health Act of 1970 pre-empts only state law that "constitutes, in a direct, clear, and substantial way, regulation of worker health and safety" and does not pre-empt "state laws of general applicability (such as laws regarding traffic safety or fire safety)," despite their demonstrable effect on occupational safety).

Only in certain special contexts, like labor law, has this Court held that incidental regulatory effects are sufficient to justify displacement of tort law. In *San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959), for example, this Court held that a state common-law damages award was preempted by the National Labor Relations Act on the ground that neither federal nor state courts possess jurisdiction over claims based on activity that is "arguably" subject to §§ 7 or 8 of the NLRA. *Id.* at 245. *Garmon* has not been read broadly.[17] But more importantly for present purposes, *Garmon* involved a special "presumption *of* federal pre-emption" relating to the primary jurisdiction of the National Labor Relations Board. *See Brown v. Hotel Employees*, 468 U.S. 491, 502 (1984); *English v. General Electric Co.*, 496 U.S. at 86-87 n.8.

No such special labor-law rule is applicable here. Instead, in

[17] *See, e.g.*, *Vaca v. Sipes*, 386 U.S. 171, 181 (1967) (*Garmon* does not extend to suits alleging breach of duty of fair representation).

this case, there is a strong presumption *against* federal preemption. *E.g.*, *New York State Conf. of Blue Cross & Blue Shield Plans*, 115 S. Ct. at 1676. A decision by Congress to establish federal regulation does not overcome that presumption and preempt state tort law. Congress legislates with the traditional understanding that federal regulatory and state tort laws are complementary systems serving different interests.

B. THE COMPENSATORY GOALS OF TORT LAW COMPLEMENT RATHER THAN CONFLICT WITH THE REGULATORY GOALS OF FEDERAL CONSUMER PROTECTION STATUTES

The regulatory system and the tort system complement each other, with one system attempting to anticipate problems before they occur and the other providing relief when consumers suffer injuries. Indeed, there is significant cross-fertilization between the tort system and regulation. For example, information obtained in individual tort suits often informs the judgment of federal regulators about whether existing standards are adequate or whether new protections should be proposed. "Obtaining accurate, relevant information" often constitutes a "central problem" for an administrative agency, particularly one like the FDA, which lacks subpoena power. Stephen Breyer, REGULATION AND ITS REFORM 103 (1982); *see also id.* at 112 ("the information problem is central and endemic to the standard-setting process"). As one scholar has observed, tort litigation is "an important social learning mechanism" because it generates data about the risks of new technologies. Lyndon, *supra*, 12 YALE J. ON REG. at 176. "[T]ort law's signals contain necessary basic messages that are not delivered through any other medium," "offer[ing] advantages that we need to account for before preempting tort law." *Id.*

Reading regulatory statutes as preempting common-law claims for damages would sacrifice the important information-gathering function of the tort system. There is no need to speculate as to the significance of this function in the context of medical devices. The Dalkon Shield tragedy, which was a primary impetus for

passage of the MDA, amply demonstrates the value of the tort system:

> Robins' dishonesty regarding the efficacy of its device, its refusal to conduct adequate testing of the Dalkon Shield, its ignoring of numerous adverse reports from physicians, its attacks on the personal character of victims in product liability lawsuits, and, ultimately, its suppression and illegal destruction of damning evidence against it were uncovered only after years of product liability litigation, some of which was unsuccessful because of Robins' suppression of critical evidence. In fact, none of this evidence was sought, or discovered, by FDA.

Adler & Mann, *supra*, 59 MO. L. REV. at 944 (footnotes omitted).

C. REGULATORY AGENCIES LIKE THE FDA DO NOT ADDRESS MATTERS OF COMPENSATION

Many commentators have analyzed the problems of "regulatory capture" or "government failure" in the context of administrative regulation of health and safety risks.[18] In this case, there is an even more powerful reason for thinking that the MDA has nothing to do with a manufacturer's state-law damages liability: the FDA has no authority or institutional competence to

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[18] *See, e.g.*, Stephen G. Breyer & Richard B. Stewart, ADMINISTRATIVE LAW AND REGULATORY POLICY 130-31 (2d ed. 1985) ("Few students of the subject would share Dean Landis' optimism about the potential use of the administrative agency. Federal administrative agencies have been subjected to an increasing barrage of criticism emanating from a variety of philosophical and political positions. Economists are concerned with the inefficiency, waste, and shortages they see caused by certain kinds of regulation. . . . Consumer groups complain that regulation is ineffective."); Stephen Breyer, REGULATION AND ITS REFORM 185 (1982) ("The defects and difficulties inherent in the system make regulation a crude weapon of government intervention."); John D. Graham and Jonathan B. Wiener, RISK VS. RISK (1995) (noting often unintentional risk tradeoffs resulting from health and safety regulation).

weigh the interests of consumers in receiving fair compensation for device-caused injuries. The FDA's expertise lies instead in assessing medical safety and effectiveness. Yet the implied premise of Medtronic's position is that the FDA, in determining whether to allow a manufacturer to market a device, should consider — as one factor in the calculus — the impact on consumers of extinguishing their state-law entitlement to compensation in the event of injury. Plainly, the FDA does not consider, and Congress never intended it to consider, this factor in passing on the manufacturer's request for device approval. If the process were otherwise, the agency would be forced to notify the public of the preemptive effect that its proposed action would have on state common-law claims and receive comments on the wisdom of displacing state-law rights to compensation. In fact, the matter is never addressed in regulatory proceedings.

D. MEDTRONIC'S ARGUMENTS ARE UNAVAILING

1. Medtronic asserts that "[c]ommon law duties have as potent a regulatory effect as state legislative enactments." Br. of Pet. Medtronic, Inc. at 14. But that statement is demonstrably unsustainable. A defendant has no choice whether to comply with a statute or a regulation; the availability of cease and desist orders ensures compliance. By contrast, the essence of tort law is that a defendant is always free not to alter its conduct and simply pay damages. Indeed, under a system of strict liability, it is sometimes rational for a defendant to pay compensatory damages rather than to change the design of its product. *See, e.g.*, Stephen Breyer, REGULATION AND ITS REFORM 175 (1982); Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW § 3.1, at 48-51 (1987).

As an empirical matter, few individual verdicts have "regulatory effect." The cases are legion in which manufacturers do not respond at all to jury awards, or respond only when hundreds or thousands of claims have been filed. For example, A.H. Robins began a campaign to inform women of the risks of the Dalkon Shield, and to encourage them to have it removed, only after years of product liability litigation. *See* Adler &

Mann, *supra*, 59 MO. L. REV. at 912 n.84, 944-45.

2. Medtronic also relies heavily on the plurality opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), which indicated that the phrase "requirement[s] or prohibition[s] . . . imposed under State law" in the Public Health Cigarette Smoking Act of 1969 encompassed state-law tort claims. 505 U.S. at 521. But this decision provides no help to Medtronic.

First, in *Cipollone* this Court recognized that "there is no general, inherent conflict" between regulation and state common law damages actions. *Id.* at 518. Indeed, the *holding* of a majority of the Court in *Cipollone* was that the 1965 Federal Cigarette Labeling and Advertising Act "is best read as having superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels," 505 U.S. at 518 — even though the 1965 preemption provision regarding advertising provided that "[n]o statement relating to smoking and health shall be *required* in the advertising of [properly labeled] cigarettes." (emphasis added). Hence, *Cipollone* does not mean that any reference to state-law "requirements" automatically preempts common-law claims for damages. And there is no evidence that in 1976 Congress would have expected such an interpretive rule.[19]

Second, the special warning label at issue in *Cipollone* bears no resemblance to the regulatory structure of the MDA. In *Cipollone*, Congress itself drafted the specific warning statements that were required to be included on cigarette packaging. Those precise words, and nothing else, were to be included. This Court held that tort claimants could not allege that Congress' language was inadequate to protect consumers.

[19] "[I]t would be particularly illogical to assume that Congress knew in 1976 when it drafted the MDA that the Supreme Court would interpret the word 'requirement' in 1992 in *Cipollone* to include common law tort claims." Adler & Mann, *supra*, 59 MO. L. REV. at 918. As Justice Breyer has commented, "[t]o change interpretive horses in midstream would defeat the expectations of the legislators who enacted a statute." Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 872 (1992).

This case presents no such issue. The FDA's role with respect to marketing notification pursuant to § 510(k) is merely to pass on the manufacturer's factual assertion that a new product is substantially *equivalent* to one already on the market. 21 U.S.C. § 360(k). Indeed, in 1982, when the § 510(k) notification for the Model 4011 lead was submitted, the MDA provided that the FDA was *not* required even to pass on Medtronic's claim of substantial equivalence and that a manufacturer like Medtronic was free to market its device 90 days after submission of the notification so long as it was not disapproved, even if the FDA did not respond to it. 21 U.S.C. § 360(k) (1982).

The § 510(k) process has always provided that the initial specifications for the design, manufacture, and labelling of the device are solely the responsibility of the manufacturer, which retains broad discretion in the matter. Thus, the FDA has declared that its acceptance of a claim of "substantial equivalence" does "not in any way denote official approval of the device," 21 C.F.R. § 807.97, and it repeated that disclaimer in the letter it issued to Medtronic. *See* App. to Br. for Lora and Michael Lohr at 10a.

Even as to devices that obtain premarket approval (PMA) pursuant to 21 U.S.C. § 360e(c)(1), the process is still very much driven and controlled by the manufacturer, which determines how the device is designed, labelled, and manufactured and which supplies all the clinical data and all the design, labelling, and manufacturing information upon which the FDA relies. Indeed, under the PMA procedure, the FDA does not mandate, or even approve, the device's design or specific manufacturing processes. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995) ("it makes little sense to hold that the FDA's premarket approval process qualifies as a 'specific requirement applicable to a particular device'"). For this reason, the Department of Justice, representing the views of the FDA, has concluded that the PMA process does not establish "requirements" under § 360k(a) and, therefore, does not have

preemptive effect.[20]

A device manufacturer's safety-related undertakings do not resemble federal safety standards so much as they resemble the undertakings of a warrantor who determines what characteristics a product will have and who promises that the product will live up to those characteristics. In *Cipollone*, this Court held that an express warranty, because it was an undertaking of the manufacturer, was not a government requirement. 505 U.S. at 525-26. The same rationale applies in this case. *Cf. Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute.").

3. At bottom, the contention that government acquiescence in a particular manufacturer's design should insulate it from tort liability — even in the absence of an explicit congressional statement to that effect — is an argument about substantive social policy, not preemption law. In essence, the complaint is that a defendant should not be forced to compensate injured persons when the federal government has tacitly approved, or at least not forbidden, its conduct. But that argument proves too much, for almost every form of private activity in or affecting commerce could be described as something the government has chosen to permit or at least not to forbid.

More fundamentally, the defendant's plea is one that should be addressed to elected legislatures and politically accountable executive officers, not to the courts. The States should be free to decide, as a matter of distributive justice, that manufacturers should bear the cost of injuries resulting even from approved devices. In addition, immunizing a defendant from liability

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[20] *See* Br. of Dept. of Justice as *amicus curiae* in *Talbott v. C.R. Bard, Inc.*, No. 94-1951, at 14 n.5 (1st Cir.) (filed Nov. 23, 1994) (indicating disagreement with the decision in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert denied*, 114 S. Ct. 84 (1993), and explaining that pre-market approval procedures are *not* "specific requirements" triggering preemption of state tort law).

whenever it obtains administrative approval for a particular design is a technology-based approach which is at odds with the contemporary preference for market-oriented incentives that continually stimulate manufacturers to innovate and develop safer products.[21] "When the courts preempt state laws without explicit congressional guidance, unelected and unaccountable officials substitute their preferences for those of the citizens of local communities. . . . [The courts] in effect assume a legislative role without accepting legislative responsibility." Judge Kenneth Starr & Judge Patrick E. Higginbotham, *et al.*, *The Law of Preemption: A Report of the Appellate Judges Conference* 48 (1991).

Preemption is all the more unjustified because state tort law has *already* accommodated the defendant's concern. It is axiomatic that standards set by federal agencies are useful benchmarks for the finders of fact in particular tort cases and that compliance with federal standards is at least evidence of due care. *See generally* Restatement (Second) of Torts § 288(c).[22] Some jurisdictions go further and mandate that compliance with such standards is a conclusive defense to tort liability, *see* Mont. Code Ann. § 69-4-201; establishes a rebuttable presumption of

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[21] *See* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357, 359 (1984) (explaining that administrative regulation is a centralized system of government control, while tort law is essentially a market-based system that employs the expertise and information already accumulated by private firms in the ordinary course of their business); Stephen Breyer, REGULATION AND ITS REFORM 105 (1982) (design standards "diminish[] incentive[s] to look for better methods" and "freeze existing technology").

[22] *See also* Paul Deuffert, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 175 (1989) ("For a hundred years courts have considered axiomatic the common law principle that, against possible liability in tort, a defendant's compliance with governmental statutes and regulations is admissible only as evidence of the defendant's exercise of due care. Therefore, such compliance generally 'does not prevent a finding of negligence where a reasonable man would take additional precautions.'") (citations omitted).

non-negligence;[23] or bars punitive damages.[24]

In recent years, nearly every State has considered — and the vast majority have implemented — legislative reform of product liability laws.[25] As this brief is submitted, Congress itself is considering legislation on the topic. The matter should be left to the politically accountable branches. Preemption law should not become, as a weapon against the States' historic role in allocating the cost of injuries, the modern-day equivalent of *Lochner v. New York*, 198 U.S. 45 (1905).

III. THIS COURT SHOULD CLARIFY THE LIMITED SCOPE OF PREEMPTION DOCTRINE

In *Cipollone*, this Court corrected the Third Circuit's misapplication of implied preemption doctrine, based on the court of appeals' impressionistic judgment that tort suits would upset the "balance" struck by Congress in the cigarette warning statutes. Unfortunately, many lower courts have misinterpreted *Cipollone* by ignoring this Court's *holding* that the 1965 cigarette act did not preempt state-law suits, as well as this Court's statement that there is "no general, inherent conflict" between tort law and regulation. 505 U.S. at 518.

Instead, many lower courts have reacted to *Cipollone* by focusing solely on the plurality's discussion of the 1969 cigarette act, automatically equating tort suits and state positive-law enactments, and readily displacing *both* under the rubric of "express preemption." The error is not confined to the MDA

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[23] *E.g.*, Model Uniform Product Liability Act § 108(A); Colo. Rev. Stat. § 13-21-403(1)(b); 735 Ill. Ann. Stat. § 2-2103; Kan. Stat. Ann. § 60-3304(a); Ky. Rev. Stat. Ann. § 411.310(2); N.D. Cent. Code § 28-01.1-05(3); Utah Code Ann. § 78-15-6(3).

[24] *E.g.*, Ariz. Rev. Stat. Ann. § 12-701; N.J. Stat. Ann. § 2A:58C-5(c); Ohio Rev. Code Ann. § 2307.80(C); Or. Rev. Stat. § 30.927; Utah Code Ann. § 78-18-1.

[25] *See, e.g.*, *Tort Reform: Camel's Nose Into State Law*, NAT'L L.J., Mar. 20, 1995, at 1; *A Changing Landscape*, 81 ABA J. 56 (Aug. 1995).

context: lower courts have employed such fallacious reasoning in pesticide,[26] boat safety,[27] and other cases as well. As a result, express preemption threatens to become the sort of freewheeling analysis that this Court rejected in *Cipollone*. Another course correction to the lower courts is in order.

1. This Court should reaffirm that express preemption is limited to the text drafted by Congress, interpreted according to the conventional tools of statutory construction and with due regard for two fundamental principles.

The first is the strong presumption against preemption arising from the constitutional concerns of federalism rooted in the Tenth Amendment and in what the Chief Justice has described as "[t]he tacit postulates" of the constitutional plan. *Nevada v. Hall*, 440 U.S. 410, 433 (1979) (Rehnquist, now C.J., dissenting).[28]

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[26] *See, e.g.*, *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993) ("If common law actions cannot survive under the 1969 cigarette law, then common law actions for labeling and packaging cannot survive under the [pesticide] law."); *see also Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995); *Taylor AG Industries v. Pure-Gro*, 54 F.3d 555, 560 (9th Cir. 1995); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747-48 (4th Cir. 1993); *Papas v. Upjohn Co.*, 926 F.2d 1019, 1025-26 (11th Cir. 1991), *vacated*, 505 U.S. 1215 (1992), *on remand*, 985 F.2d 516, 517-18 (11th Cir.), *cert. denied*, 114 S. Ct. 300 (1993).

[27] *See, e.g.*, *Edwards v. Murray Chris-Craft Sportboats, Inc.*, 873 F. Supp. 618, 621 (M.D. Fla. 1994) (design claim expressly preempted — even in the face of a savings clause providing that "[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law" — because "[t]o allow a jury to award damages in this case under state common law for [defendant's failure] to incorporate positive flotation in the boat would be to establish, continue in effect, or enforce a law or regulation imposing a performance or other safety standard").

[28] *See, e.g.*, *Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991) ("[I]nasmuch as this Court in *Garcia [v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528 (1985)] has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise. '[T]o give

The second principle is that Congress legislates against a background understanding of the significant distinction between the tort and regulatory systems. Accordingly, a congressional decision to displace state positive-law enactments should not be equated with a decision to bar state-law tort suits for damages. Indeed, the presumption against preemption is especially strong when Congress has failed to provide a separate federal remedy for a person injured by tortious conduct, as in the MDA.

2. This Court should also reaffirm the limited scope of implied preemption and reject the analysis proffered by Medtronic at 46 n.24 of its brief. When Congress has expressly addressed the matter of preemption in a specific statutory provision whose meaning can be ascertained through the conventional tools of statutory construction — applied with reference to the two principles outlined above — preemption analysis should ordinarily be at an end. *See Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1488 (1995) (establishing "an inference that an express pre-emption clause forecloses implied pre-emption").

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the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'") (quoting Laurence Tribe, AMERICAN CONSTITUTIONAL LAW § 6-25, at 480 (2d ed. 1988)); *see also U.S. Term Limits, Inc. v. Thornton*, 115 S. Ct. 1842, 1887 n.12 (1995) (Thomas, J., joined by Rehnquist, C.J., and O'Connor and Scalia, JJ., dissenting) (quoting the same sentence of AMERICAN CONSTITUTIONAL LAW and describing *Gregory* as "applying this argument"); Judge Kenneth Starr & Judge Patrick E. Higginbotham, *et al.*, *The Law of Preemption: A Report of the Appellate Judges Conference* 50-51 (1991) (discussing plain statement requirement in preemption context).

CONCLUSION

The judgment of the Court of Appeals should be reversed insofar as it holds that the MDA preempts any of the state-law claims for damages asserted by respondents/cross-petitioners Lora and Michael Lohr.

Respectfully submitted.

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IN THE

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BRIEF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES, COUNCIL OF STATE GOVERNMENTS, NATIONAL ASSOCIATION OF COUNTIES, NATIONAL LEAGUE OF CITIES, INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION, AND U.S. CONFERENCE OF MAYORS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS/CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 preempt state tort law claims for injuries caused by a defective medical device.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	v
INTEREST OF THE *AMICI CURIAE*	1
SUMMARY OF ARGUMENT	3
ARGUMENT	6
I. THE MEDICAL DEVICE AMENDMENTS DO NOT PREEMPT STATE TORT LAW CLAIMS FOR INJURIES CAUSED BY A DEFECTIVE MEDICAL DEVICE	6
A. The MDA Does Not Preempt State Tort Remedies	9
1. Congress Did Not Have "The Clear And Manifest Purpose" To Supersede The States' Traditional Systems Of Tort Liability	9
2. The Requirement That Congress Have "The Clear And Manifest Purpose" To Preempt State Law Is A Crucial Political Safeguard Of Federalism	12
B. Even If State Tort Law Is Subject To Preemption, The FDA Correctly Limited The Scope Of Preemption	16
1. The FDA's Interpretation Of Section 360k(a) Is Reasonable And Entitled To Deference	16
2. The Lohrs' Common Law Claims Are Not Preempted Because No Federal "Requirements" Apply To The Pacemaker Lead That Caused Ms. Lohr's Injuries	20

TABLE OF CONTENTS—Continued

	Page
II. PREEMPTION OF STATE COMMON LAW DAMAGES ACTIONS WOULD LEAVE PERSONS INJURED BY MEDICAL DEVICES WITHOUT ANY MEANS OF OBTAINING COMPENSATION AND WOULD DEFEAT CONGRESS' PURPOSE OF PROTECTING CONSUMERS	21
A. Section 510(k) Of The MDA Does Not Ensure That Medical Devices Are Safe And Does Not Establish A Private Cause Of Action For Damages Caused By A Defective Medical Device	22
B. State Law Actions Are The Only Means Of Providing Compensation For Individuals Injured By Defective Medical Devices	26
CONCLUSION	29

TABLE OF AUTHORITIES

Cases

	Page
Atascadero State Hosp. v. Scanlon, 473 U.S. 234 (1985)	12
Bailey v. Johnson, 48 F.3d 965 (6th Cir. 1995)	24
Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)	4, 8, 16
Cipollone v. Liggett Industries Group, Inc., 505 U.S. 504 (1992)	*passim*
CSX Transportation, Inc. v. Easterwood, 507 U.S. 658 (1993)	7, 21
Dellmuth v. Muth, 491 U.S. 223 (1989)	12
Department of Rev. v. ACF Industries, 114 S.Ct. 843 (1994)	7
English v. General Electric Corp., 496 U.S. 72 (1990)	12, 27
Federal Energy Regulatory Commission v. Mississippi, 456 U.S. 742 (1982)	13-14
Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3534 (U.S. Jan. 26, 1996) (No. 95-1214)	23-24
Freightliner Corp. v. Myrick, 115 S.Ct. 1483 (1995)	5, 20
Garcia v. San Antonio Metropolitan Transit Authority, 469 U.S. 528 (1985)	13
Garner v. Teamsters Union, 346 U.S. 485 (1953)	27, 28
Gregory v. Ashcroft, 501 U.S. 452 (1991)	3, 12, 13
Haudrich v. Howmedica, Inc., 642 N.E.2d 206 (Ill. App. 1994), *aff'd on other grounds*, 1996 Ill. LEXIS 8 (Ill. Jan. 18, 1996)	25
Hillsborough County v. Automated Medical Lab., Inc., 471 U.S. 707 (1985)	16
Ingersoll-Rand Co. v. McClendon, 498 U.S. 133 (1990)	27
Mackey v. Lanier Collection Agency and Service, Inc., 486 U.S. 825 (1988)	26
NationsBank of North Carolina, N.A. v. Variable Annuity Life Insurance Co., 115 S.Ct. 810 (1995)	8
New York v. United States, 326 U.S. 572 (1946)	13
New York v. United States, 505 U.S. 144 (1992)	13

TABLE OF AUTHORITIES—Continued

Page

New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 115 S.Ct. 1671 (1995) ..... *passim*

Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n, 461 U.S. 190 (1983) 26

Pennhurst State School & Hosp. v. Halderman, 451 U.S. 1 (1981) 12-13

Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41 (1987) .. 27

Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947) 3, 6-7, 12

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) 25-26, 26-27, 28

Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321) 24

United Auto Workers v. Wisconsin Employment Relations Bd., 336 U.S. 245 (1949) 28

United Constr. Workers v. Laburnum Constr. Corp., 347 U.S. 656 (1954) 6, 27, 28

United States v. Bass, 404 U.S. 336 (1971) 3

United States v. Lopez, 115 S.Ct. 1624 (1995) 3, 13

Will v. Michigan Dept. of State Police, 491 U.S. 58 (1989) 12

Statutes and Regulations

21 U.S.C. § 360c(a) (1) (A)-(C) 22

21 U.S.C. § 360c(a) (1) (C) 22

21 U.S.C. § 360c(f) (1) (A) 23

21 U.S.C. § 360e(b) (1) (B) 23

21 U.S.C. § 360e(d) (2) 22-23

21 U.S.C. § 360h(a) 11

21 U.S.C. § 360h(b) 11

21 U.S.C. § 360h(c) 11

21 U.S.C. § 360h(d) 11

21 U.S.C. § 360k(a) ..... *passim*

21 U.S.C. § 360k(b) 10

21 C.F.R. § 808.1(d) 5, 8, 17, 20, 21

21 C.F.R. § 808.1(d) (1) 17

21 C.F.R. § 860.3(c) (3) 22

TABLE OF AUTHORITIES—Continued

Page

Sherman Food, Drug, and Cosmetic Law, 1970 Cal. Stat. Ch. 1573, § 5, *codified at* Cal. Health & Safety Code, §§ 26600 *et seq.*, *repealed by* 1995 Cal. Stat. Ch. 415, § 169 9

Legislative Materials

42 Fed. Reg. 30,383 (June 14, 1977) 4, 11, 17, 19

43 Fed. Reg. 18,661 (May 2, 1978) ..... *passim*

45 Fed. Reg. 67,321 (Oct. 10, 1980) 9

S. Rep. No. 33, 94th Cong., 2d Sess. (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070 21

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) .. 11, 21, 22

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House Comm. on Energy and Commerce, 103rd Cong., 1st Sess. *Less Than The Sum Of Its Parts: Reforms Needed In The Organization, Management, And Resources Of The Food And Drug Administration's Center For Devices And Radiological Health* (Comm. Print 1993) 23

Other Authorities

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Edward M. Swartz, *Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments*, 18 De Paul L. Rev. 348 (1969) 9

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INTEREST OF THE *AMICI CURIAE*

Amici, organizations whose members include state, county, and municipal governments and officials throughout the United States, have a compelling interest in legal issues that affect state and local gov-

ernments. This case presents a recurring question that lies at the core of *amici*'s interests: the relationship between a federal statute and state tort law.

The States, through the mechanism of tort liability, have long protected their citizens by requiring that manufacturers compensate those injured by products as a result of defective design, manufacture, or labeling. The availability of state remedies is of obvious importance to persons injured by defective medical devices. In enacting the Medical Device Amendments of 1976 (MDA), Congress intended to enhance consumer protection, not to undermine it. Accordingly, it adopted a narrow preemption provision that it intended to be interpreted in a manner consistent with the MDA's overriding purpose of protecting consumers.

Medtronic's interpretation of the MDA's preemption provision would turn congressional intent on its head by stripping away the protection that state law affords consumers of medical devices, even in areas where no federal safeguards exist. Such an interpretation would leave consumers with far less protection than they had prior to the MDA's enactment. Moreover, it is wholly at odds with the FDA's longstanding regulatory pronouncements and principles of federalism.

Because of the importance of these issues to *amici* and their members, *amici* submit this brief to assist the Court in its resolution of the case.[1]

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[1] The parties have consented to the filing of this brief *amicus curiae*. Letters indicating their consent have been filed with the Clerk of the Court.

SUMMARY OF ARGUMENT

1. Manufacturers of medical devices are subject to liability under state tort law unless Congress had " 'the clear and manifest purpose' " to supersede the States' " 'historic police powers' " to protect the health and safety of their citizens. *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S.Ct. 1671, 1676 (1995) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

Congress did not state clearly in the Medical Device Amendments (MDA) any intention to preempt state tort remedies for consumers injured by medical devices, and " 'unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance.' " *United States v. Lopez*, 115 S.Ct. 1624, 1631 (1995) (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)); *see also Gregory v. Ashcroft*, 501 U.S. 452, 460-64 (1991). This requirement that Congress state clearly its intention to expand national power at the expense of the States is a critical means of protecting the States' role in our federal system of government. *See id.* Medtronic's argument that the MDA totally supplants state common law remedies is flatly inconsistent with the requirement that Congress state clearly such a fundamental reordering of state and national power.

In section 360k(a) Congress prohibited any state "requirement" for a medical device "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device . . . ." 21 U.S.C.

§ 360k(a). There is simply no evidence that Congress intended a state "requirement" to include state common law tort actions. Quite to the contrary, the sparse legislative history suggests that in section 360k(a) Congress was concerned only with the appropriate accommodation of state statutes and regulations with the MDA and not with state common law. *See* 42 Fed. Reg. 30,383 (June 14, 1977). Extrapolating this general language to preempt state common law tort actions violates the presumption against preemption and would absolve Congress from the responsibility to decide openly to leave consumers without any remedy for injuries caused by defective medical devices.

Even if the MDA could be interpreted expansively to provide for preemption of some aspects of state common law, the Lohrs' common law claims are not preempted. Congress, of course, never addressed the precise question whether particular common law claims were preempted or the extent of preemption because it did not intend to preempt state common law. In these circumstances, the FDA's longstanding interpretation of the preemptive effect of the MDA, as reflected in its existing regulatory pronouncements, is reasonable and entitled to deference. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984).

The FDA correctly turned to the structure and purpose of the MDA to determine the scope of preemption of state law. *See Travelers*, 115 S.Ct. at 1679-80. The FDA found that Congress' purpose of protecting consumers from unsafe and ineffective medical devices would be defeated if state law was preempted before the agency issued "compensating" regulations under the MDA. 43 Fed. Reg. 18,661, 18,663 (May 2, 1978). In interpreting section 360k

(a), the FDA correctly recognized that the promulgation of "specific" federal law "requirements" under the MDA is the prerequisite for preemption of state law. 21 C.F.R. § 808.1(d); *cf. Freightliner Corp. v. Myrick*, 115 S.Ct. 1483, 1487 (1995). The Lohrs' common law claims are not preempted because there are no federal "requirements" that apply to the pacemaker lead that caused Ms. Lohr's injuries. *See* Lohr Br. 39-45.

2. Medtronic's expansive view of the preemptive scope of the MDA runs directly counter to Congress' purpose of enhancing consumer protection. Under such a reading, consumers would be stripped of the protection afforded by state common law even where no federal regulatory protections have been adopted to replace them. This interpretation would leave individuals who have been injured or killed by defective medical products without any remedy, solely because of the enactment of a federal law which was supposed to enhance protections for users of medical devices. Such a result is plainly contrary to Congress' intent.

The section 510(k) process, through which the great majority of Class III medical devices (including the Medtronic Model 4011 pacemaker lead) reach the market, does not provide substantive protection to consumers against unsafe products. Rather, it guarantees consistency of treatment for equivalent medical devices. Where, as here, a device is equivalent to one that was already on the market when the MDA was enacted, the 510(k) process does nothing more than carry forward the congressional decision to "grandfather" such a pre-existing medical device —without making any inquiry into its safety.

Nor does the MDA provide any private right of action for those injured by devices entering the market through the 510(k) process. State law, therefore, provides the only means of obtaining relief for injuries or fatalities sustained because of defects in the large numbers of medical devices entering the market through this process. Under Medtronic's interpretation of the MDA, however, all consumers of medical devices would be deprived of these essential state law remedies. Such an interpretation is plainly untenable, as it would create a broad area devoid of any legal protection. *See, e.g., United Constr. Workers v. Laburnum Constr. Corp.*, 347 U.S. 656, 663-64 (1954).

ARGUMENT

I. THE MEDICAL DEVICE AMENDMENTS DO NOT PREEMPT STATE TORT LAW CLAIMS FOR INJURIES CAUSED BY A DEFECTIVE MEDICAL DEVICE

Last Term, in a unanimous decision, this Court restated the framework for analysis of preemption issues. *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S.Ct. 1671 (1995). The Court addresses claims that state laws are preempted by express preemption provisions like section 360k(a)[2] "with the starting presumption that Congress does not intend to supplant state law." *Travelers*, 115 S.Ct. at 1676 (citations omitted). "[W]here federal law is said to bar state action in fields of traditional state regulation," such as health and safety, the Court proceeds on the " 'assumption

[2] Section 521(a) of the Medical Device Amendments of 1976 is codified at 21 U.S.C. § 360k(a) and is reproduced in the appendix to the Lohrs' opening brief at pp. 1a-2a.

that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' " *Travelers*, 115 S.Ct. at 1676 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Congress did not have the clear and manifest purpose in the MDA to preempt state common law. The Lohrs' claims accordingly are not preempted.

This presumption against preemption and the corollary requirement that Congress demonstrate its preemptive purpose clearly and unambiguously are grounded on fundamental "principles of federalism." *See Department of Revenue of Oregon v. ACF Industries*, 114 S.Ct. 843, 850 (1994); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 532-33 (1992) (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part). They serve the vital "interest of avoiding unintended encroachment on the authority of the States." *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

Congress did not state clearly in the MDA any intention to preempt state common law claims. Although Congress expressly addressed the issue of preemption in section 360k, it spoke only "with generality." *See Travelers*, 115 S.Ct. at 1677. Judicial extrapolation of the general preemptive language of section 360k to preempt state common law claims would "read the presumption against pre-emption out of the law" in an area—the protection of citizens' health and safety—where state police powers are central. *See Travelers*, 115 S.Ct. at 1677. It would also violate the rule that when courts address an express preemption provision, they "must fairly but—in light of the strong presumption against preemption—nar-

rowly construe [its] precise language." *Cipollone*, 505 U.S. at 523.

Where the text of the statute does not show any "clear and manifest purpose" to preempt all state tort law liability, the Court "move[s] on" to the "structure and purpose" of the statute "as a guide to the scope of the state law that Congress understood would survive." *Travelers*, 115 S.Ct. at 1676-77. Given the structure and purpose of the MDA, section 360k(a) expresses Congress' intent to preempt only positive state law in limited circumstances. If, however, section 360k(a) is construed more broadly to encompass some aspects of state common law, the Court should defer to the FDA's determination of the appropriate accommodation of state law and federal law. *See* 21 C.F.R. § 808.1(d).

Congress did not state clearly any intent to preempt state common law claims and, therefore, it did not address the precise question of the extent of preemption. Under these circumstances, the agency's interpretation of the preemptive effect of the statute is reasonable and should be given controlling weight. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984); *see NationsBank of North Carolina, N.A. v. Variable Annuity Life Insurance Co.*, 115 S.Ct. 810, 813-14 (1995). At most, as the FDA has ruled, the MDA preempts state law only to the extent that the agency has established specific requirements applicable to particular medical devices. Here, the Lohrs' common law claims are not preempted because the FDA has not established any specific regulations applicable to the pacemaker lead that is the subject of this case.

A. The MDA Does Not Preempt State Tort Remedies

1. *Congress Did Not Have "The Clear And Manifest Purpose" To Supersede The States' Traditional Systems Of Tort Liability*

When Congress enacted the Medical Device Amendments in 1976, a substantial body of state tort law was applicable to medical devices. Claims for injuries caused by defective medical devices could be pursued under a variety of state common law doctrines, including negligence, breach of warranty, and strict liability in tort. *See, e.g.*, Edward M. Swartz, *Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments*, 18 De Paul L. Rev. 348, 358 (1969); Ann M. Caldwell, Note, *Products Liability and Medical Devices: Diagnosis and Cure*, 87 Dick. L. Rev. 779, 781-90 (1983); R.D. Hursh, Annotation, *Liability of Manufacturer or Seller For Injury Caused By Medical and Health Supplies, Appliances, and Equipment*, 79 A.L.R. 2d 401 (1961); Romualdo P. Eclavea, Annotation, *Products Liability In Connection With Prosthesis Or Other Product Designed To Be Surgically Implanted In Patient's Body*, 1 A.L.R. 4th 923, 924-25 (1980). Moreover, as Congress itself recognized, some States—most notably California—had enacted statutes and regulations governing medical devices. *See, e.g.*, Sherman Food, Drug, and Cosmetic Law, 1970 Cal. Stat. Ch. 1573, § 5, *codified at* Cal. Health & Safety Code, §§ 26600-26693, 26801-26851, *repealed by* 1995 Cal. Stat. Ch. 415, § 169; 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980); *see also* Robert S. Adler and Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924-25 & n. 131 (1994).

Although Congress explicitly addressed some aspects of the relation between the new federal statute and this preexisting body of state law in 21 U.S.C. §§ 360k and 360h(d), it did not have any intention, much less any clear and manifest purpose, to preempt state tort law. Sections 360k and 360h(d) demonstrate no intent to preempt state tort law. In section 360k, Congress spoke to the issue of preemption only at a very high level of generality, and it charged the FDA with substantial responsibility to work out the details of the accommodation of state and federal law. In section 360h(d), Congress expressly recognized that medical device manufacturers and others are subject in certain circumstances to liability under state law.

Section 360k(a), the express preemption provision of the MDA, plainly does not support any conclusion that Congress intended to preempt state tort law. In subsection (a), Congress prohibited any state "requirement" for a medical device "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device . . . ." 21 U.S.C. § 360k(a). In the following subsection, Congress narrowed the scope of preemption by authorizing the FDA to exempt certain state requirements. 21 U.S.C. § 360k(b). The statute does not define either a state "requirement" or a "requirement" under the MDA. There is simply no evidence that Congress intended a state "requirement" to include state common law tort actions. Consequently, there is no basis to conclude that Congress had "the clear and manifest purpose" to supersede the States' traditional tort laws.

Quite to the contrary, the sparse legislative history suggests that in section 360k Congress was concerned only with the appropriate accommodation of state statutes and regulations with the MDA and not with state common law. *See* 42 Fed. Reg. 30,383 (June 14, 1977). Congress focused on state and local "regulation" of medical devices and in particular on California's Sherman Food, Drug, and Cosmetic Law, which "require[d] premarket approval of all new medical devices, require[d] compliance of device manufacturers with good manufacturing practices and authorize[d] inspection of establishments which manufacture devices." H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). Although the Committee Report noted that such state "regulations" might unduly burden interstate commerce and might be preempted under subsection (a), it also stated that the "requirements imposed under the California statute serve as an example of requirements" that the FDA is authorized to exempt from preemption under subsection (b). *Id.* at 46.

Section 360h(d) also confirms that Congress did not have any "clear and manifest purpose" to preempt state common law. The FDA has power to notify the public and health professionals of unreasonable risks associated with medical devices and to order manufacturers to repair or to replace the device, to refund the purchase price, and to pay reimbursements. 21 U.S.C. §§ 360h(a), (b), (c). The statute expressly provides that compliance with these repair, replacement, refund, and reimbursement orders "shall not relieve any person from liability under Federal or State law." *Id.* § 360h(d).

In the absence of any clear and manifest congressional purpose to supersede the States' traditional

systems of tort liability, the Court should not construe the MDA to accomplish this result. *See English v. General Electric Corp.*, 496 U.S. 72, 83 (1990). Instead, the Court should hold that a state "requirement" in section 360k does not include state common law causes of action and force Congress to be politically accountable for any decision to insulate manufacturers of medical devices from tort liability. In determining the scope of preemption, and in many other contexts vital to the preservation of the federal-state balance, judicial enforcement of the rule that Congress must state clearly its intention to substantially reorder federal-state relations is a crucial means of protecting the States' role in our federal system.

2. *The Requirement That Congress Have "The Clear And Manifest Purpose" To Preempt State Law Is A Crucial Political Safeguard Of Federalism*

The Court has held repeatedly that the historic police powers of the States are not preempted "unless that was the clear and manifest purpose of Congress." *Travelers*, 115 S.Ct. at 1676 (quoting *Rice*, 331 U.S. at 230). The Court has imposed an analogous clear statement rule in many other contexts. *See Gregory v. Ashcroft*, 501 U.S. 452, 460-61 (1991). The Court, for example, requires a clear statement of congressional intent to subject the States to damages suits in state courts. *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989). Congress must make its intent to abrogate the States' Eleventh Amendment immunity "unmistakably clear in the language of the statute." *Dellmuth v. Muth*, 491 U.S. 223, 227-28 (1989) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985)). Congress must state clearly the conditions of federal grants that impose costs on the States. *Pennhurst*

State School & Hosp. v. Halderman, 451 U.S. 1, 17 (1981). Congress must also state clearly its intention to regulate the States as States. *Gregory*, 501 U.S. at 460-61, 467; *see New York v. United States*, 326 U.S. 572, 584-85 (1946) (Rutledge, J., concurring) (Congress should state "explicitly" its intention to apply a generally applicable tax to a state function).

An unambiguous expression of congressional intent to displace state law is an essential means of protecting the States' role in our federal system. *See Gregory*, 501 U.S. at 461. The requirement of a clear statement of congressional intent to alter the balance of authority between the federal government and the States permits the electorate to hold Congress accountable. Congress' political accountability is in turn the foundation of judicial deference to congressional ordering of federal-state relations.

Although *amici* have frequently argued otherwise, the Court has held that federalism limits on Congress' legislative powers are enforced primarily by the political process and not by the judicial process. *See Garcia v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528, 550-54 (1985); *but see United States v. Lopez*, 115 S.Ct. 1624 (1995). Under the Court's decisions, this judicial deference to Congress' adjustment of the balance of national and state power in our federal system is appropriate to the extent that Congress is politically accountable to the national electorate. *New York v. United States*, 505 U.S. 144, 168-69 (1992); *see Lopez*, 115 S.Ct. at 1638-39 (Kennedy, J., concurring); *id.* at 1651-52 (Souter, J., dissenting); *Federal Energy Regulatory Comm'n v. Mississippi*, 456 U.S. 742, 787 (1982) (O'Connor, J., con-

curring in the judgment in part and dissenting in part). The electorate, however, cannot hold Congress accountable unless Congress indicates, clearly and unambiguously its intent to supplant the States' authority.

This case illustrates the importance of the clear statement rule. If Congress had indicated "the clear and manifest purpose" to insulate manufacturers of replacement joints, antiwrinkle treatments, intraocular lenses, heart catheters, heart valves, pacemakers, and other medical devices from all liability under state tort law, the Medical Device Amendments of 1976 would have been subject to a very different constellation of political forces. Congress probably would have rejected the MDA if it unambiguously provided that patients injured by defective medical devices would not have any means of obtaining compensation under state law. Indeed, there would have been no possibility of enactment if, as discussed below, Congress also stated clearly that it was not creating any alternative federal provision for compensation to fill the void created by preempting state common law actions.

The question, put simply, is whether Congress, by an explicit statement, or the Court, by extrapolation of a generally worded express preemption provision, should supplant the States' traditional systems of tort liability and immunize manufacturers of defective medical devices from all state law claims for compensation. The Court should not make this decision for Congress; it should require Congress to take political responsibility for any decision to bar the States from protecting the health and safety of their citizens under their traditional systems of tort liability. In

short, in the absence of a much clearer direction from Congress, the Court should not drastically alter the federal-state balance by construing the term "requirement" in section 360k(a) to include state common law.[8] There is no support for Medtronic's argument

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[8] The requirement that Congress have a "clear and manifest purpose" to preempt state tort law is completely consistent with this Court's recent decision in *Cipollone*. In that case, six members of the Court held that the phrase "requirement or prohibition . . . imposed under State law" in an express preemption provision included both positive state enactments and state common law. 505 U.S. at 520-24 (Stevens, J., joined by Rehnquist, C.J., White and O'Connor, JJ.) and at 548-49 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part).

Nonetheless, seven members of the Court recognized that the express preemption provision must be read in the light of either the presumption against preemption or the corollary requirement that Congress must make its purpose to preempt state law "clear and manifest." Writing for the Court, Justice Stevens expressly recognized the requirement that Congress make its intention to preempt the States' historic police powers "clear and manifest." *Id.* at 516. In a separate opinion, Justice Blackmun, joined by Justices Kennedy and Souter, found that the statutory language did not embrace state common law because Congress did not "'clearly' or 'manifestly' exhibit[] an intent to preempt state common-law damages actions." *Id.* at 534. (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part). Although Justice Stevens did not directly apply this "clear and manifest purpose" rule, his plurality opinion expressly applied the presumption against preemption and concluded that state common law could be subject to preemption only in light of special factors and circumstances not present in the MDA. *Id.* at 520-24; *see* Adler and Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 923 (substantial differences between statute at issue in *Cipollone* and the MDA).

that section 360k(a) immunizes medical device manufacturers from liability under all state common law tort doctrines.

Not only does the term "requirement" in section 360k(a) fall far short of any indication that Congress had "the clear and manifest purpose" to preempt all state tort law, it is best read, in light of the structure and purpose of the MDA, as an expression of Congress' intent to preempt only state positive law. As the Lohrs argue persuasively, Congress, in section 360k(a), intended to preempt only state statutes and regulations. *See* Lohr Br. 16-34. Even if the term "requirement" in the MDA can be interpreted more expansively, however, to include some aspects of state common law, it is appropriate to defer to the agency's interpretation of section 360k(a) as a guide to the scope of state law that Congress understood would survive.

B. Even If State Tort Law Is Subject To Preemption, The FDA Correctly Limited The Scope Of Preemption

1. The FDA's Interpretation Of Section 360k(a) Is Reasonable And Entitled To Deference

The standard for judicial deference to an agency's interpretation of a statute that it administers is well-settled. If "Congress has not directly addressed the precise question at issue," courts defer to an agency's interpretation unless it is "arbitrary, capricious, or manifestly contrary to the statute." *Chevron*, 467 U.S. at 843-44. *See Hillsborough County v. Automated Medical Labs, Inc.*, 471 U.S. 707, 714-15 (1985) (Court defers to FDA determination that regulation setting standards for collection of blood plasma does not preempt state and local regulation).

As discussed above, Congress did not state clearly an intent to preempt any state common law claims; therefore, it could not have addressed the precise question whether the particular common laws claims in this case are preempted. Even if the term "requirement" in section 360k(a) could properly be read to include state common law as well as state statutes and regulations, Congress did not determine precisely the extent to which state "requirements" would be preempted by the MDA. Instead, Congress spoke to the issue of preemption only at a very high level of generality.

The FDA has taken a clear position regarding the preemptive scope of the MDA: "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . ." 21 C.F.R. § 808.1(d). In addition, the FDA has identified several types of state and local requirements that are not " 'requirements applicable to a device' within the meaning of section 521(a) of the act," and which are therefore not preempted. *Id.; see, e.g.*, 21 C.F.R. § 808.1(d)(1) (state and local requirements of general applicability are not preempted). The FDA has further elaborated on its interpretation of the MDA's preemption provision in pronouncements made in the course of rulemaking, emphasizing the need to avoid an expansive view of preemption that would undermine the congressional purpose of enhancing consumer protection. *See, e.g.*, 43 Fed. Reg. 18,661, 18,663 (May 2, 1978); 42 Fed. Reg. 30,383 (June 14, 1977).

This longstanding interpretation of the preemptive effect of section 360k(a) is reasonable and entitled to deference. The agency carefully examined the structure and the purpose of the MDA in order to determine the scope of state law that Congress intended would survive. The FDA found that Congress' purpose of protecting consumers from unsafe and ineffective medical devices would be defeated if state law was preempted before the agency could adopt "compensating" regulations under the act.[4] The agency also found that preemption of state law before issuance of specific federal regulations, which could take a considerable amount of time, would create a "regu-

[4] In promulgating its final preemption regulation, the FDA noted:

> The entire thrust of the [MDA] is to provide FDA with new and additional authority to assure that only safe and effective medical devices are permitted on the market. There is nothing in the legislative history to indicate Congress intended that the [MDA] should result in less protection for the public, which would be the natural consequence of State Controls being eliminated during the considerable period of time it will take for FDA to implement fully the new authorities provided in the [MDA].
>
> [I]nterpretations urged by the comments [that all state and local requirements were preempted as of the effective date of the MDA] would provide less public protection from unsafe and ineffective medical devices because State and local regulation of medical devices would be reduced or eliminated before compensating FDA regulations could become effective.

43 Fed. Reg. 18,661, 18,663 (May 2, 1978) (citations omitted).

latory hiatus" or a "regulatory void."[5] Recognizing that Congress intended to promote safety and to avoid any undue burden on interstate commerce, the FDA specifically found that its interpretation of section 360k(a) "will not cause an undue burden on interstate commerce because it merely allows State and local requirements to continue in effect until FDA establishes a national policy on the regulation of specific devices." 43 Fed. Reg. 18,661, 18,663 (May 2, 1978).

Although the FDA focused exclusively on the accommodation of state statutes and regulations with the MDA, its conclusions apply with equal force to accommodation of state common law with the MDA. Congress' purpose of protecting consumers from unsafe and ineffective medical devices would be defeated if the tort law incentive to manufacture safe and effective medical devices was removed by preemption

[5] The FDA noted when it proposed section 808.1(d), the preemption regulation which was subsequently adopted without change, that:

> [T]he Commissioner has narrowly construed the preemption provisions so that section 521(a) of the act [21 U.S.C. § 360k(a)] preempts State and local requirements only when a particular Federal requirement becomes applicable to a particular device by operation of the act. This avoids disruption of vital State and local programs relating to the regulation of medical devices and reduces the possibility of a regulatory hiatus that could result if State or local requirements were considered preempted prior to the time FDA implemented Federal requirements. The potential for such a regulatory void is real since it will require several years for FDA to implement fully its device regulatory programs.

42 Fed. Reg. 30,383 (June 14, 1977).

before the FDA adopted specific "compensating" regulations. There would be a "regulatory void" if the common law's indirect inducement to manufacture safe products was canceled before the FDA established any alternative safety mechanism. Moreover, until the FDA acts, the mere continuation of state tort law liability could not cause an "undue" burden on interstate commerce because "there is no greater burden . . . than if the [MDA] had not been enacted." 43 Fed. Reg. 18,661, 18,663 (May 2, 1978). Ironically, if state tort liability for a particular medical device were preempted before the FDA had promulgated specific requirements for that device, consumers would have less protection after enactment of the MDA than before.

Given these concerns, the FDA reasonably determined that section 360k(a) preempts state law "only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . ." 43 Fed. Reg. 18,661, 18,662 (May 2, 1978); 21 C.F.R. § 808.1(d). In interpreting section 360k(a), the FDA correctly recognized that the promulgation of "specific" federal law "requirements" under the MDA is the prerequisite for preemption of state law. *Cf. Freightliner Corp. v. Myrick*, 115 S.Ct. 1483, 1487 (1995).

2. *The Lohrs' Common Law Claims Are Not Preempted Because No Federal "Requirements" Apply To The Pacemaker Lead That Caused Ms. Lohr's Injuries*

Amici adopt, without repeating, the Lohrs' arguments that only device-specific federal requirements have preemptive force. *See* Lohr Br. 13-14, 39-45;

see also 21 C.F.R. § 808.1(d). Because no device-specific federal regulations apply to any of the Lohrs' claims, there can be no preemption of the state law governing those claims. *See* Lohr Br. 42-45.

* * * *

In short, the court of appeals failed to establish that Congress had "the clear and manifest purpose" to preempt state tort law, and it extended the preemptive effect of section 360k far beyond the bounds intended by Congress and beyond the bounds identified by the FDA. To the extent that the court of appeals held that the Lohrs' common law claims are preempted, its judgment is an "unintended encroachment on the authority of the States," *CSX*, 507 U.S. at 664, and should be reversed.

II. PREEMPTION OF STATE COMMON LAW DAMAGES ACTIONS WOULD LEAVE PERSONS INJURED BY MEDICAL DEVICES WITHOUT ANY MEANS OF OBTAINING COMPENSATION AND WOULD DEFEAT CONGRESS' PURPOSE OF PROTECTING CONSUMERS

Congress, spurred to action by the Dalkon Shield tragedy, enacted the MDA to protect consumers from dangerous and ineffective medical devices. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976); S. Rep. No. 33, 94th Cong., 2d Sess. 1-2, 6-7 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1070-72, 1075-76. Congress intended that consumers would be protected both by laws and regulations that prevent unsafe or ineffective medical devices from reaching the market, and by pre-existing mechanisms for compensation in the event that they are injured by a defective device. There is no evidence that Congress thought regulation alone was sufficient to protect consumers or that com-

pensation and regulation were somehow antithetical. Congress never even debated whether to deny compensation to individuals injured or killed by defective medical devices and to relegate the task of consumer protection exclusively to regulatory review and civil or criminal enforcement of regulations.

A decision by this Court construing section 360k(a) to preempt state common law tort remedies, however, would, in effect, make the decision that Congress declined to make. Preemption of state tort actions would result in a complete denial of compensation because there is no private cause of action under the MDA for damages, and it would relegate the protection of many consumers, like Ms. Lohr, exclusively to federal regulatory provisions for safety and effectiveness that have sometimes proved ineffective. *See generally Br. Am. Cur.* American Association of Retired Persons *et al.*

A. Section 510(k) Of The MDA Does Not Ensure That Medical Devices Are Safe And Does Not Establish A Private Cause Of Action For Damages Caused By A Defective Medical Device

The MDA divides medical devices into three categories on the basis of the level of risk that they create for consumers. *See* 21 U.S.C. §§ 360c(a)(1)(A)-(C); H.R. Rep. No. 853 at 34. Life-preserving devices, like pacemakers and pacemaker leads, fall into Class III, the class of medical devices involving the highest risk. 21 U.S.C. § 360c(a)(1)(C); *see* 21 C.F.R. § 860.3(c)(3). Class III devices may be subject to a pre-market approval (PMA) process requiring a determination by the FDA, on the basis of data submitted by the manufacturer, that there is "reasonable assurance" that the device is safe and effective.

21 U.S.C. § 360e(d)(2). Most Class III devices, however, have not yet been subject to the PMA process and instead come to the market under the section 510(k) process. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A); *see* S. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307 ("[O]ver 80 percent of the devices that are potentially the most dangerous (Class III), enter the market on the basis of a claim by the manufacturer that they are 'substantially equivalent' to a device already on the market.").

Under section 510(k), a manufacturer can market a Class III device if the FDA finds that it is "the 'substantial equivalent' of an already-marketed device, including a device grandfathered into the market." Medtronic Pet. App. 5a (opinion of court of appeals) (quoting 21 U.S.C. § 360e(b)(1)(B)). An FDA finding of "substantial equivalence" under section 510(k) is not a finding of safety and effectiveness. *See, e.g.*, House Comm. on Energy and Commerce, 103d Cong., 1st Sess., *Less Than The Sum Of Its Parts: Reforms Needed In The Organization, Management, And Resources Of The Food And Drug Administration's Center For Devices And Radiological Health* 8-9 (Comm. Print 1993).

Medtronic's Model 4011 pacemaker lead came to the market under the section 510(k) process as the substantial equivalent of a pre-MDA or "grandfathered" product. The FDA's decision to permit Medtronic to market its Model 4011 pacemaker lead was not a finding of safety and effectiveness. *See* Lohr Br. at 7-8. The FDA simply determined that Model 4011, like all other devices that enter the market under section 510(k), was "as safe as a predi-

cate device that itself [may be] unreasonably dangerous." *See Feldt v. Mentor Corp.*, 61 F.3d 431, 438 n.12 (5th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3534 (U.S. Jan. 26, 1996) (No. 95-1214).

Although there is no regulatory determination of the safety and effectiveness of medical devices that reach the market under the section 510(k) process, the MDA does not include any provision for compensation for those injured by these devices. There is no express private cause of action for damages under the MDA, and no federal court has ever recognized an implied private right of action under the Food, Drug, and Cosmetic Act, the statute which incorporates the MDA. *See Bailey v. Johnson*, 48 F.3d 965, 966-68 (6th Cir. 1995) (collecting cases). The Act relies exclusively on civil and criminal enforcement by the FDA, and it leaves open only a faint prospect of compensation in rare cases—a restitution order in a criminal case. *See Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29-30 (1st Cir. 1995) ("Courts in future criminal proceedings will, or should, be aware that restitution may be the only redress for those harmed by manufacturers who have failed to comply with the provisions of the MDA."), *petition for cert. filed*, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321).

In the circumstances of this case—where the FDA determined no more than that a particular medical device was the substantial equivalent of another device that was never subject to any pre-market approval and where there is no federal cause of action for damages caused by the device—preemption of state tort law remedies would deprive consumers harmed by defective devices of all means of redress. It is implausible that Congress, whose purpose was

to protect consumers, would deny consumers compensation for injuries caused by products that are simply the substantial equivalent of grandfathered products manufactured before the effective date of the MDA and that were never subject to any pre-market determination of their safety and effectiveness. *See* Adler and Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 930, 940-45. As one court recently observed,

> If safety was Congress' primary purpose, it would be strange for Congress to eliminate the safety aspects inherent in tort litigation by destroying tort litigation in the entire country with the same statute it passed to promote safety. It would be stranger still for Congress to take such dramatic action without even mentioning it as a consequence of the passage of a bill that was debated for years.

Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 211 (Ill. App. 1994) (citations omitted), *aff'd on other grounds*, 1996 Ill. LEXIS 8 (Ill. Jan. 18, 1996).

Nonetheless, Medtronic urges the Court to construe section 360k(a) to achieve this implausible and unfair result. *See* Medtronic Br. 30-46. As Medtronic notes, many courts of appeals, lower courts, and state courts have construed section 360k(a) broadly to preempt a wide array of state tort law actions. *Id.* at 37 n.19. These decisions have left consumers without any protection against defective medical devices and without any means of obtaining compensation for deaths and injuries caused by defective medical devices. In cases that would have involved similarly harsh results, however, this Court has rejected the proposition "that Congress would, without comment, remove all means of judicial recourse for those in-

jured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

B. State Law Actions Are The Only Means Of Providing Compensation For Individuals Injured By Defective Medical Devices

This case falls squarely within a line of cases holding that state common law remedies are not preempted where federal law provides no comparable or alternative remedy.[6] *E.g.*, *Silkwood*, 464 U.S. at

[6] There is an analogous doctrine that courts should not interpret federal statutes to create a regulatory void. For example, in *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983), the Court interpreted several statutory provisions explicitly allocating regulatory authority between the States and a federal regulatory agency in order to avoid creating a regulatory void and to preserve from preemption a traditional area of state regulation. The Court first found that the Atomic Energy Acts of 1946 and 1954 gave the federal government exclusive authority over radiological safety standards for commercial nuclear power plants and that Congress had left "no role . . . for the States." 461 U.S. at 206-07. After noting that Congress had not given the federal government any authority over the economic aspects of nuclear power generation, the Court, in keeping with the presumption against preemption, concluded that the States must have this type of regulatory authority because "[i]t is almost inconceivable that Congress would have left a regulatory vacuum." 461 U.S. at 207-08. *See also Mackey v. Lanier Collection Agency and Service, Inc.*, 486 U.S. 825 (1988) (preemption of one state garnishment law does not create a regulatory void because a second state garnishment law is not preempted).

The rule that state common law remedies are not preempted where federal law provides no comparable or alternative remedy is also consistent with this Court's cases finding that state laws are superseded where "the bite of pre-emption" has been eased by congressional provision of a substitute for the preempted state laws. *See Cipollone*, 505 U.S. at 541

251; *United Constr. Workers v. Laburnum Constr. Corp.*, 347 U.S. 656, 663-64 (1954); *see Cipollone*, 505 U.S. at 541-42 (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part); *cf. English*, 496 U.S. at 87-90 (federal administrative remedy does not preempt state common law action for intentional infliction of emotional distress).

For example, in *United Constr. Workers v. Laburnum Constr. Corp.*, the Court held that the Labor Management Relations Act (LMRA) did not preempt a state common law tort action for damages caused by conduct that was an unfair labor practice under the federal statute. 347 U.S. at 663-64. Although the Court had previously held that state courts could not enjoin unfair labor practices, *Garner v. Teamsters Union*, 346 U.S. 485 (1953), it refused to extend that holding to bar a state tort action. The Court explained *Garner* on the ground that Congress had provided a federal administrative remedy which was a substitute for injunctive relief. In *Laburnum*, however, the Court found that "Congress has neither provided nor suggested any substitute for the traditional state court procedure for collecting damages for injuries caused by tortious conduct." 347 U.S. at 663-64. There was no provision in the LMRA for an employer to obtain compensation for the tortious conduct of a union, and the case presented " 'an instance

(Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part); *see Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 142-45 (1990) (comprehensive federal civil enforcement scheme fills void created by preemption of state common law claim); *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54-56 (1987) (same).

of injurious conduct which the National Labor Relations Board is without express power to prevent and which therefore either is "governable by the State or it is entirely ungoverned."'" 347 U.S. at 664 (quoting *Garner*, 346 U.S. at 488) (quoting *United Auto Workers v. Wisconsin Employment Relations Bd.*, 336 U.S. 245, 254 (1949)).

Just as the Court was unwilling to find implied preemption of state common law remedies in *Laburnum*, it was unwilling in *Silkwood* to preempt a state common law tort action for punitive damages. The *Silkwood* Court recognized that Congress intended "to prohibit the States from regulating the safety aspects of nuclear development," but it found no bar to a state law action against a federally licensed nuclear plant for injuries and property damage caused by plutonium contamination. 464 U.S. at 250. Given "Congress' failure to provide any federal remedy," the Court found that "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." 464 U.S. at 251.

There is no reason why this Court should construe section 360k(a) to leave consumers of defective medical devices without any means to obtain compensation for their injuries. A narrow construction of section 360k(a) is required by the presumption against preemption and by the requirement of a clear and manifest congressional purpose to preempt state law. In this case, like *Laburnum* and *Silkwood*, there are no substitute federal private causes of action, express or implied, to fill the void if state tort law is preempted. There is no basis for believing that Congress, in enacting the MDA, intended to leave consumers without any compensation for injuries caused by

defective medical devices. It would stand the presumption against preemption on its head to insist that the States, in the exercise of their historic police powers, must overcome the inertia of the federal legislative process to secure statutory relief from the court of appeals' unduly expansive interpretation of section 360k(a). To the contrary, the burden is on Congress to make an explicit decision displacing the States' traditional systems of tort liability. Congress did not make that decision in the MDA.

CONCLUSION

The judgment of the court of appeals that the Lohrs' state law negligent design and strict liability claims are not preempted should be affirmed. The judgment that their negligent manufacture and failure to warn claims are preempted should be reversed.

Respectfully submitted,

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Supreme Court of the United States

October Term, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent

v.

LORA LOHR and MICHAEL LOHR,

Respondents/Cross-Petitioners,

On Writ Of Certiorari
To The United States Court Of Appeals
For The Eleventh Circuit

BRIEF AMICUS CURIAE OF THE STATE OF CALIFORNIA IN SUPPORT OF RESPONDENTS/ CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

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QUESTION PRESENTED

Under the Medical Device Amendments to the Federal Food, Drug and Cosmetics Act, must requirements be device-specific in order to preempt state law?

TABLE OF CONTENTS

Page

INTEREST OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT..... 4

STATUTORY OVERVIEW 5

ARGUMENT 10

I. THE EXPRESS PREEMPTION PROVISION OF THE MDA SHOULD BE CONSTRUED NARROWLY TO PRESERVE THE ABILITY OF THE STATES TO PROTECT THEIR CITIZENS FROM HARM..... 10

II. ONLY DEVICE SPECIFIC REQUIREMENTS UNDER THE MDA PREEMPT STATE LAW .. 11

A. The FDA Interpretation is Consistent with the Language of the Statute 11

B. The FDA Interpretation is the Only Interpretation Consistent with the Structure and Intent of the MDA..... 14

CONCLUSION 17

TABLE OF AUTHORITIES

Page

CASES

Anguiano v. Du Pont, 44 F.3d 806 (CA 9 1995)..... 14

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) [120 L.Ed.2d 407, 112 S.Ct. 2608]..... 10

Committee of Dental Amalgam Alloy Manufacturers and Distributors and Dentsply, Inc. v. Stratton and Lungren, 871 F.Supp. 1278 (S.D. Cal. 1994) 2, 3

Duvall v. Bristol-Myers-Squibb, 65 F.3d 392 (CA 4 1995)..... 14

English v. Mentor, 67 F.3d 477 (CA 3 1995) 14

Feldt v. Mentor Corp., 61 F.3d 431 (CA 5 1995)..... 14

Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707 (1985)..... 10

Jacobs v. DuPont, 67 F.3d 1219 (CA 6 1995) 14

Kennedy v. Collagen Corp., 67 F.3d 1453 (CA 9 1995) 14

Lamontagne v. E.I. Du Pont, 41 F.3d 846 (CA 2 1994) 14

Larsen v. Pacesetter Systems, Inc., 837 P.2d 1273 (Hawaii 1992) 14

Lohr v. Medtronic, 56 F.3d 1335 (CA 11 1995) .. 4, 5, 14, 15

Mendes v. Medtronic, 18 F.3d 13 (CA 1 1995)..... 14

Moore v. Kimberly-Clark Corp., 867 F.2d 243 (CA 5 1989)..... 14

National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988 (CA 8 1994)..... 14

TABLE OF AUTHORITIES – Continued

Page

New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 795 (N.J. 1978) 14

Reeves v. Acromed, 44 F.3d 300 (CA 5), *cert.denied*, 132 L.Ed.2d 258, 115 S.Ct. 2251 (1995) 14

Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947) 10

Smith v. Pingree, 651 F.2d 1021 (CA 5 1981) 14

FEDERAL STATUTES

United States Code

21 U.S.C. § 351 5

21 U.S.C. § 351(a)(1) 6

21 U.S.C. § 352 5

21 U.S.C. § 352(a),(f) 6

21 U.S.C. § 352(f) 2, 6, 13

21 U.S.C. § 360 5

21 U.S.C. § 360c(a)(1)(B) 7

21 U.S.C. § 360c(a)(1)(C) 7

21 U.S.C. § 360c(a)(1)(B),(C) 4, 7, 16

21 U.S.C. § 360c(f)(1) 9

21 U.S.C. § 360c(i)(1)(A) 9

21 U.S.C. § 360c(h) 5

21 U.S.C. § 360e(b)(1)(A) 9

TABLE OF AUTHORITIES – Continued

Page

21 U.S.C. § 360f 5

21 U.S.C. § 360h 5

21 U.S.C. § 360i 5

21 U.S.C. § 360j 5

21 U.S.C. § 360(k) 9

21 U.S.C. § 360k(a) 11, 16

FEDERAL REGULATIONS

Code of Federal Regulations

21 C.F.R. § 801.109 2

21 C.F.R. § 801.109(c) 6

21 C.F.R. §§ 801.403 *et seq.* 7, 8

21 C.F.R. § 801.410(d)(2) 8

21 C.F.R. § 801.420 14

21 C.F.R. § 801.420(c)(1) 8

21 C.F.R. § 801.427 8

21 C.F.R. § 808.1(d) 3, 12

21 C.F.R. § 814.1(c)(1) 9

21 C.F.R. § 820.1 *et seq.* 6

21 C.F.R. § 820.5 6

21 C.F.R. § 820.25 6

21 C.F.R. § 820.40 6

TABLE OF AUTHORITIES – Continued

Page

21 C.F.R. § 820.60 6

21 C.F.R. § 872.3700 2

Federal Register

42 Fed. Reg. 9186 (1977) 13

42 Fed. Reg 30383 (1977) 12

42 Fed. Reg. 30384 (1977) 13

52 Fed. Reg. 10082 (1987) 9

52 Fed. Reg. 30089 (1987) 2

STATE STATUTES AND REGULATIONS

California Health & Safety Code

Health & Saf. Code §§ 25249.5 *et seq* 1

Health & Saf. Code § 25249.6 1

California Code of Regulation

22 Cal. Code of Reg. § 12601(b) 1

OTHER AUTHORITIES

Robert S. Adler and Richard A. Mann *Preemption and Medical Devices The Courts Run Amok* 59 Mo. L. Rev. 895 (1994) 9, 15

H.R. Rep. No. 808 101st Cong., 2d Sess. 14 *reprinted in* 1990 U.S.C.C.A.N. 6307 9

H.R. Rep. No. 853, 94th Cong. 2d Sess. 8-10 (1976) 15

INTEREST OF AMICUS CURIAE

Pursuant to Supreme Court Rule 37.5, *Amicus Curiae*, the State of California, submits this brief in support of respondents/cross-petitioners Lora and Michael Lohr. The State of California has a strong and specific interest in preserving its traditional police power authority to enforce state statutes and regulations that protect public health and welfare. The Eleventh Circuit's decision erodes that traditional area of state regulation in a manner that leaves the citizens of the various states open to potentially devastating harm from medical devices.

One aspect of the preemption issue before this Court is of particular interest to the State. In 1986 the People of the State of California enacted the Safe Drinking Water and Toxic Enforcement Act ("Proposition 65"), California Health & Safety Code sections 25249.5 *et seq.* ("Cal. H&SC") Proposition 65 is a general "Right to Know" statute which applies to a list of several hundred chemicals that are known carcinogens and/or reproductive toxins. The statute requires that anyone, in the course of doing business, who exposes any individual to certain levels of the listed carcinogens or reproductive toxins, must first give a clear and reasonable warning to the exposed individual. Cal. H&SC § 25249.6. The warning requirement applies whether the exposure occurs from smokestack emissions, through ingestion of food, through the use of a consumer product,[1] or in any other

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[1] For consumer products containing reproductive toxins, the "safe harbor" warning language is: "**WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." 22 California Code of Regulations § 12601(b).

environment or circumstance, including through the use of a medical device.

In 1994, the federal district court for the Southern District of California ruled that Proposition 65, as it applies to dental mercury, a Class I device,[2] was preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetics Act ("MDA"). *Committee of Dental Amalgam Alloy Manufacturers and Distributors and Dentsply, Inc. v. Stratton and Lungren*, 871 F.Supp. 1278 (S.D. Cal. 1994). The court concluded that the general labeling requirements contained in 21 U.S.C. section 352(f) and 21 C.F.R. section 801.109, that apply to all medical devices or all prescription devices, were "specific requirements" that preempted Proposition 65 and prevented enforcement of that statute's warning requirement. *Dental Amalgam*, 871 F.Supp. at 1284. The State appealed and the case is pending before the Court of Appeals of the Ninth Circuit. (Nos. 94-56508 and 94-56512) While the decision in the *Dental Amalgam* appeal involves a Class I medical device, it is also possible that exposures to Proposition 65 chemicals may result

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[2] When placed in teeth dental mercury exposes the dental patient to quantities of mercury, a listed reproductive toxin under Proposition 65, thereby making it potentially subject to the warning requirements of Proposition 65.

Dental mercury was originally proposed to be classified as a Class II medical device. While recognizing that elemental mercury is a poison that posed a threat to patients with allergic reactions and to dental professionals, the FDA stated that a performance standard would not alleviate these risks and therefore classified the device as Class I. 21 C.F.R. § 872.3700; 52 Fed. Reg. 30089 (1987).

from the use of Class II and Class III medical devices. The Court's ruling therefore may equally affect the ability of the State to enforce Proposition 65 as it applies to these more dangerous devices.

One of the central questions at issue in the case before this Court – whether federal requirements under the MDA must be device specific in order to preempt state requirements – is the same as the question that is currently pending in the *Dental Amalgam* appeal.[3] Thus, the Court's ruling here may not only determine the ongoing validity of state common law tort claims as they apply to medical devices, it may equally determine the ability of the states to enforce public health and safety statutes.

Because the *Dental Amalgam* decision raises the question of preemption of statutory enactments, rather than common law claims, the State of California is filing this separate amicus brief to address that portion of the Eleventh Circuit decision that applies to statutory enactments as well as common law claims.

The State of California urges this Court to rule that only device-specific requirements under the MDA may preempt state requirements, and that the general requirements applicable to all devices or to broad categories of devices under the MDA do not preempt state law.

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[3] The State has also asserted that Proposition 65 is a requirement of general applicability not directed at medical devices and therefore is not preempted pursuant to 21 C.F.R. § 808.1(d).

SUMMARY OF ARGUMENT

This Court is faced with the intersection of federal law intended to protect consumers from harm caused by medical devices and the traditional police power of the States to regulate in the area of health and safety. While the case before the Court involves common law claims, its ruling may affect statutory enactments as well, making it more difficult or impossible for the States to perform their traditional role in safeguarding the public welfare.

In enacting the MDA, Congress established three categories of medical devices ranging from the least regulated (Class I) to the most regulated (Class III). Congress also established a two part structure of regulation. On the one hand there are the broad general controls applicable to all devices. These do not reflect any knowledge by the FDA of the particular hazards of a device or how to ensure the safety of that device. In marked contrast to the general controls are the special controls directed at specific devices and reflecting the FDA's study of the particular device and determination of how to ensure that the device is safe.

In enacting this statutory scheme, Congress specifically found that the general controls applicable to all devices were insufficient to ensure the safety and effectiveness of the Class II and III devices. 21 U.S.C. §§ 360c(a)(1)(B)(C).

The Eleventh Circuit in *Lohr v. Medtronic*, 56 F.3d 1335, 1351 (CA 11 1995) held that the general controls applicable to all devices preempt state law and prevent the States from regulating particular medical devices.

Furthermore, even though thousands of the most dangerous devices are now marketed pursuant only to the general controls and these general controls were deemed by Congress to be inadequate, under *Lohr* the states are still prohibited from exercising their traditional police powers to provide needed protection to their citizens.

Contrary to the *Lohr* decision, Congress did not intend to eradicate state law protection until the FDA exercises its own regulatory control of specific devices. It is only device-specific regulation that will assure consumers of the safety of particular medical devices and only device-specific regulation that relieves the states of their traditional duties to protect public health and welfare. Thus, contrary to the decision by the *Lohr* court, the skeletal outlines of regulation contained in the general controls do not preempt state law.

STATUTORY OVERVIEW

The State of California will not repeat the detailed description of the MDA provided to the Court by the Lohrs. A brief description, however, of the structure of regulation in the MDA is necessary to set the stage for the argument below.

The MDA's general controls, defined by 21 U.S.C. section 360c(h) as those controls authorized by sections 351, 352, 360, 360f, 360h, 360i and 360j, are applicable to all medical devices and are the skeletal outline of the regulatory scheme. The statutory general controls contain broad requirements not directed at particular devices. For example, the general controls prohibit adulterated

devices that contain filthy, putrid or decomposed substances or that do not conform to current good manufacturing practice; or prohibit misbranded devices if the labeling is false or misleading or does not contain "adequate directions for use" and warnings against use in pathological conditions. 21 U.S.C. §§ 351(a)(1), 352(a),(f).

The FDA has enacted regulatory counterparts to the statutory general controls. While these regulations are sometimes more detailed in subject matter than the statutory provisions, they are not device specific and retain the open-ended quality of the statute. For example, 21 C.F.R. section 801.109(c), one of the "Exemptions from Adequate Directions for Use," states that prescription medical devices need not comply with the "adequate directions for use" requirement of 21 U.S.C. section 352(f) if the label contains use information, and warnings, *i.e.* "hazards, contraindications, side effects, and precautions . . . . " Similarly 21 C.F.R. sections 820.1 *et seq.* simply instruct manufacturers to prepare quality assurance programs, to have sufficient personnel with appropriate training, to use buildings of suitable design and space, to use appropriately designed equipment, and the like. 21 C.F.R. §§ 820.5, 820.25, 820.40, 820.60.

In each instance, the general controls were promulgated with no knowledge of a specific device or its dangers and do not inform the manufacturer of exactly what must be done with a particular device to protect the public. Thus, the general controls initially leave to the manufacturer the decision on how to ensure the safety of a particular device. The manufacturer remains free to argue to the FDA and, if necessary, to the courts, that the general controls did not impose a particular requirement

on him or his device or that whatever actions he took were sufficient to comply with the statutory requirements.

Congress specifically found that the general controls applicable to all devices were insufficient to assure the safety and effectiveness of the more dangerous Class II and III devices[4] and therefore authorized that these devices would be subject to device specific special controls (Class II) or the premarket approval process (Class III). 21 U.S.C. § 360c(a)(1)(B),(C).

Unlike the general controls, the device specific requirements reflect careful scrutiny by the FDA of a particular device and a studied determination of how to make the device safe and effective. The contrast between the general controls, whether statutory or regulatory, and the device specific requirements is illuminated by the requirements contained in 21 C.F.R. sections 801.403 *et seq.*, a regulatory Subpart entitled "Special Requirements for ***Specific*** Devices." (emphasis added). This Subpart

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[4] Class II devices are those for which the general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device and for which the FDA can establish special controls. 21 U.S.C. § 360c(a)(1)(B).

Class III devices are those which present an unreasonable risk of illness or injury or which are used in sustaining human life or preventing impairment of human health and whose safety and effectiveness cannot be assured by the general or special controls. 21 U.S.C. § 360c(a)(1)(C).

contains, for example, device specific warning requirements,[5] testing requirements,[6] and labeling requirements.[7]

The Congressional determination that the general controls are not adequate to ensure the safety and effectiveness of the Class II and Class III devices is particularly significant because, at the time the MDA was enacted, thousands of devices were already on the market. The FDA lacked the resources to classify and regulate all of the preexisting devices[8] and to process the

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[5] Denture reliners: "*Warning* – For temporary use only. Long term use of this product may lead to faster bone loss, continuing irritation, sores and tumors. For Use Only Until A Dentist Can be Seen." (21 C.F.R. § 801.403.)

Intrauterine Devices: "Contraindications – IUDs should not be inserted when the following conditions exist: 1. Pregnancy or suspicion of pregnancy. 2. Abnormalities of the uterus resulting in distortion of the uterine cavity. . . . " 21 C.F.R. § 801.427.

[6] Impact resistant sun glasses: "In the impact test, a 5/8-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a 5/8-inch diameter. . . . " 21 C.F.R. § 801.410(d)(2).

[7] Hearing aids: "The User Instructional Brochure accompanying each hearing aid shall contain the following information. . . . : (i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment. (ii) Information on the function of all controls intended for user adjustment. (iii) A description of any accessory that may accompany the hearing aid. . . . " 21 C.F.R. § 801.420(c)(1).

[8] As the FDA noted in 1987, it lacked the resources to establish performance standards for all devices already classified or being classified as Class II devices. Therefore, "[u]nder the amendments, FDA is using the regulatory controls

premarket approval requirements for all of the preexisting Class III devices. The preexisting devices, therefore, including the most dangerous Class III devices, were "grandfathered" into the statute and were permitted to remain on the market subject only to the general controls. *See* 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Furthermore, any new devices that were substantially equivalent to the grandfathered devices were similarly allowed to enter the market through the "510(k) premarket notification process" and were subject only to the general controls applicable to all devices. *See* 21 U.S.C. § 360(k), 360c(f)(1), 360c(i)(1)(A); H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307; Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 914 (1994).

Despite the substantial passage of time since the enactment of the MDA, a large portion of all devices, including the most dangerous Class III devices, have entered the market through the premarket notification process and simply remain subject to the general controls applicable to all devices until such time as the FDA acts to classify and regulate them. H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307. *See also* Adler and Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 914 and n. 98. These preexisting and substantially equivalent Class II and Class III medical devices therefore remain in regulatory limbo – subject to

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of class I to regulate a device classified into class II until a performance standard is established under sections 514 of the act (21 U.S.C. 360d) for a class II device." 52 Fed. Reg. 10082 (1987).

the general controls of the MDA but not yet subject to any device-specific requirements and not yet fully evaluated by the FDA for safety and effectiveness.

ARGUMENT

I. THE EXPRESS PREEMPTION PROVISION OF THE MDA SHOULD BE CONSTRUED NARROWLY TO PRESERVE THE ABILITY OF THE STATES TO PROTECT THEIR CITIZENS FROM HARM

Preemption analysis begins with the basic assumption that "the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504; 112 S.Ct. 2608, 2617; 120 L.Ed.2d 407, 422 (1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In determining whether an express preemption provision preempts state law, this Court in *Cipollone* held that courts must construe the express language of the statute "in light of the presumption against the pre-emption of state police power regulations." 112 S.Ct. at 2618; 120 L.Ed.2d at 424.

The presumption against preemption is particularly strong when applied to state health & safety regulations. "[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Medical Laboratories, Inc.* 471 U.S. 707, 719 (1985).

As noted above, while this Court is faced with the preemption of common law claims, its rulings may

equally affect state statutory enactments like Proposition 65, intended to warn citizens about exposures to toxic chemicals. If Congress intends to preempt statutes like Proposition 65 and to restrain the states from regulating in the traditional area of health and safety, it must do so expressly. Any expression of Congressional intent that is less than clear and manifest, and any ambiguity in the statute, must be construed against preemption.

II. ONLY DEVICE SPECIFIC REQUIREMENTS UNDER THE MDA PREEMPT STATE LAW

A. The FDA Interpretation is Consistent with the Language of the Statute

Preemption analysis begins with the express language of the statute. The preemption provision of the MDA states that:

> no State . . . may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C. § 360k(a).

While the statute does not expressly define a "requirement applicable under this chapter to the device" that is intended to be preemptive, the language at least suggests that Congress was focused on particular devices

and the requirements applicable to those particular devices.

Consistent with this language, as well as with the strong presumption against preemption of state health and safety statutes, it has been the longstanding interpretation of the FDA that preemption only applies when the FDA has enacted a device specific requirement.

> State or local requirements are preempted only when the Food and Drug Administration has established ***specific*** counterpart regulations or there are other ***specific*** requirements applicable to a ***particular*** device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the ***specific*** Food and Drug Administration requirements. 21 C.F.R. § 808.1(d) (Emphasis added).

Throughout the years, prompted in part by a concern with avoiding a "regulatory hiatus,"[9] the FDA has reiterated its view that preemption only results from device specific requirements. Thus, the Commissioner of the FDA noted that he believed that:

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[9] "Consistent with his understanding of the intent of Congress, the Commissioner has narrowly construed the preemption provisions so that section 521(a) of the act preempts State and local requirements ***only when a particular Federal requirement becomes applicable to a particular device by operation of the act***. This avoids disruption of vital State and local programs relating to the regulation of medical devices and reduces the possibility of a regulatory hiatus that could result if State or local requirements were considered preempted prior to the time FDA implemented Federal requirements." 42 Fed. Reg. 30383 (1977) (emphasis added).

> Congress intended section 521(a) [360k(a)] of the act to preempt only those different or additional State and local requirements that relate to matters already governed by ***specific, established Federal requirements applicable to a specific device***. 42 Fed. Reg. 9186 (1977) (emphasis added).

The FDA went on to note that:

> a preempting FDA requirement will become applicable to a device within the meaning of section 521(a) [360k(a)] only after FDA takes a regulatory or administrative action involving the ***application of a particular requirement of the act to a particular device.*** 42 Fed. Reg. 30384 (1977) (emphasis added).

In the same discussion, the FDA provided a concrete example of the manner in which it envisioned preemption applying:

> For example, as noted in the recent regulation relating to professional and patient labeling and conditions for sale of hearing aids, State or local requirements that relate to such labeling requirements or conditions for sale ***will be preempted by section 521(a) on the effective date of the hearing aid regulation***. . . . *Id.* (emphasis added).

In other words, it is not the broad, general labeling requirements contained in 21 U.S.C. section 352(f) or 21 C.F.R. section 801.1 *et seq.* that preempt state law; it is the

device specific requirements, such as that contained in 21 C.F.R. section 801.420, that are preemptive.[10]

B. The FDA Interpretation is the Only Interpretation Consistent with the Structure and Intent of the MDA

Ultimately, the goal of preemption analysis is to determine the intent of Congress. Congress enacted the

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[10] Until relatively recently, most case law was consistent with the FDA interpretation and the courts based their preemption analysis only on device specific requirements. *See, e.g., Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-59 (CA 9 1995); *Jacobs v. DuPont*, 67 F.3d 1219, 1234-1236 (CA 6 1995); *Anguiano v. Du Pont*, 44 F.3d 806, 810 (CA 9 1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 990 (CA 8 1994); *Lamontagne v. E.I. Du Pont*, 41 F.3d 846, 853, 855 (CA 2 1994); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (CA 5 1989); *Smith v. Pingree*, 651 F.2d 1021, 1024 (CA 5 1981); *Larsen v. Pacesetter Systems, Inc.* 837 P.2d 1273, 1282 (Hawaii, 1992); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795, 812-13 (N.J., 1978).

The Eleventh Circuit in *Lohr*, is part of a series of decisions which have failed to recognize the authority of the states to protect the health and safety of their citizens and the strong presumption against preemption of that authority. *See, e.g., English v. Mentor*, 67 F.3d 477, 482 (CA 3 1995); *Duvall v. Bristol-Myers-Squibb*, 65 F.3d 392, 399 (CA 4 1995); *Feldt v. Mentor Corp.*, 61 F.3d 431, 435 (CA 5 1995); *Reeves v. Acromed*, 44 F.3d 300, 305 (CA 5), *cert.denied*, 132 L.Ed. 2d 258, 115 S.Ct. 2251 (1995); *Mendes v. Medtronic*, 18 F.3d 13, 17-18 (CA 1 1994). To the extent that these recent decisions find preemption based on the general controls applicable to all devices or to broad categories of devices, they are inconsistent with the earlier caselaw, with the recent decisions of the Second, Sixth, Eight and Ninth Circuits and with the interpretation of the FDA.

MDA in 1976 against a particular backdrop – the deaths and injuries that had occurred to many American women of child bearing age from the Dalkon Shield Intrauterine Device, a medical device largely unregulated by the Food and Drug Administration. *See* H.R. Rep. No. 853, 94th Cong. 2d Sess. 8-10 (1976) ("House Report"); Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 911-12. As a result of that and similar tragedies with other unregulated devices, Congress passed the MDA, with the expressed intent to increase consumer protection and safeguard the public health by assuring the safety and effectiveness of medical devices. House Report at 12.

The Eleventh Circuit in *Lohr v. Medtronic*, 56 F.3d 1335, 1351 (CA 11 1995) held that the general controls under the MDA preempt state requirements. Under the *Lohr* analysis, the FDA need do nothing more than issue broad, general controls applicable to all devices in order to prevent the states from exercising their traditional police powers to protect their citizens. In fact, the broader and more general the control, the greater the preemption. Even if the state has studied and examined a particular device, is aware of its dangers and knows what is needed to remedy those dangers, the state remains powerless. It can impose no device specific warning requirement and no device specific manufacturing requirement, simply because the FDA has issued a broad instruction applicable to all devices to provide necessary warnings and to use good manufacturing processes.

The anomaly set up by *Lohr* is made even more apparent when the Court considers that there are thousands of Class II and Class III devices being marketed

subject only to the general controls, controls that Congress specifically determined ***were not sufficient to ensure the safety and effectiveness of those devices***. 21 U.S.C. 360c(a)(1)(B),(C).

It is difficult to imagine that Congress established a system of general controls that it deemed to be inadequate for certain classes of devices, permitted the large majority of those devices to be marketed subject only to the general controls and then simultaneously preempted state safety and health statutes that offer consumers some additional measure of protection. If general controls are deemed to be preemptive, medical devices subject only to the general controls, including those recognized by the FDA as presenting a potential unreasonable risk of danger, would suddenly be freed from state regulation in vital areas such as warning and manufacturing processes and subject only to the same federal requirements used to regulate crutches, tongue depressors and bandages, requirements which Congress itself has recognized to be insufficient to assure the safety and effectiveness of these devices.

Given the real-world backdrop to the MDA – the deaths, miscarriages and sterility that resulted from an unregulated medical device – it is improbable that Congress intended that the general controls applicable to all devices would preempt state law and that dangerous devices would be freed from state regulation only to be ruled by the broadest and vaguest of federal requirements. Rather, the FDA interpretation of section 360k(a), that only device specific requirements can preempt state law, is a reasonable construction of the statute that comports with Congressional intent to increase consumer

protection. In order for there to be preemption of traditional state police powers to enforce health and safety statutes, the FDA must exercise its regulatory authority to study and examine a particular device and determine exactly what device-specific requirements are necessary to protect the safety of citizens relying on the device. Then, and only then, can the states relax their vigilance, knowing that the FDA has asserted full regulatory control over the device and will protect state citizens from unnecessary harm.

CONCLUSION

Thousands of dangerous medical devices remain in what might best be termed regulatory limbo, subject only to the general controls applicable to all devices, controls that Congress has determined are not adequate to assure the safety and effectiveness of these devices. Until such time as the FDA can bring to bear on these devices its full regulatory oversight and impose device-specific controls and standards, the states must be left free to fill in the interstices of the regulatory scheme and continue to protect the health and safety of their citizens. Amicus Curiae, the State of California, therefore requests that this Court rule that only device-specific requirements preempt state law and the general controls applicable to all devices or

to broad categories of devices do not preempt the police powers of the states.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF *AMICUS CURIAE* GENERAL MOTORS CORPORATION IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act expressly preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

TABLE OF AUTHORITIES iii

INTEREST OF *AMICUS CURIAE* 1

INTRODUCTION 4

SUMMARY OF ARGUMENT 6

ARGUMENT 8

I. THE FDCA'S EXPRESS PREEMPTION CLAUSE APPLIES TO "REQUIREMENTS" IMPOSED BY STATE COMMON LAW AS WELL AS THOSE IMPOSED BY STATE LEGISLATIVE AND REGULATORY ENACTMENTS 8

II. THE ORDINARY PURPOSE OF A SAVINGS CLAUSE IS TO AVOID ANY INFERENCE OF "FIELD" PREEMPTION, AND IN ANY EVENT ITS GENERAL LANGUAGE DOES NOT CONTROL SPECIFIC PROVISIONS OF AN EXPRESS PREEMPTION CLAUSE 14

III. PREEMPTION ISSUES ARE MATTERS OF PURE STATUTORY CONSTRUCTION AND THUS ARE NOT GOVERNED BY THE ESTABLISHED PRESUMPTION AGAINST "OCCUPY THE FIELD" PREEMPTION 19

CONCLUSION 23

TABLE OF AUTHORITIES

Pages

Cases

Adams Fruit Co. v. Barrett,
494 U.S. 638 (1990) 18

Atascadero State Hosp. v. Scanlon,
473 U.S. 234 (1985) 21

Brown v. Hotel & Restaurant Employees and Bartenders Int'l Union,
468 U.S. 491 (1984) 17, 22

Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992) ..... *passim*

English v. General Elec. Co.,
496 U.S. 72 (1990) 21

Erie R.R. v. Tompkins,
304 U.S. 64 (1938) 7, 13, 14

FMC Corp. v. Holliday,
498 U.S. 52 (1990) 22

Freightliner Corp. v. Myrick,
115 S. Ct. 1483 (1995) 22

Gregory v. Ashcroft,
501 U.S. 452 (1991) 21

International Paper Co. v. Ouellette,
479 U.S. 481 (1987) 17

TABLE OF AUTHORITIES - Continued

Pages

John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank,
114 S. Ct. 517 (1993) 16

Malone v. White Motor Corp.,
435 U.S. 497 (1978) 21

Morales v. Trans World Airlines, Inc.,
504 U.S. 374 (1992) 17, 22

Napier v. Atlantic Coast Line R.R.,
272 U.S. 605 (1926) 20

Pennsylvania R.R. v. Puritan Coal Mining Co.,
237 U.S. 121 (1915) 16

Pilot Life Ins. Co. v. Dedeaux,
481 U.S. 41 (1987) 17

Reid v. Colorado,
187 U.S. 137 (1902) 20

Rice v. Santa Fe Elevator Corp.,
331 U.S. 218 (1947) 21

San Diego Bldg. Trades Council, Millmen's Union, Local 2020 v. Garmon,
359 U.S. 236 (1959) 11

Savage v. Jones,
225 U.S. 501 (1912) 20

Swift v. Tyson,
41 U.S. (16 Pet.) 1 (1842) 14

TABLE OF AUTHORITIES - Continued

Pages

Tebbetts v. Ford Motor Co.,
665 A.2d 345 (N.H. 1995),
cert. denied, 116 S. Ct. 773,
reh'g denied, 1996 WL 77746 (1996) 22

Texas & Pacific Ry. Co. v. Abilene Cotton Oil Co.,
204 U.S. 426 (1907) 17

Constitutional Provisions, Statutes and Rules

U.S. Const., art. VI, cl. 2 ..... *passim*

Federal Cigarette Labeling and Advertising Act,
Pub. L. 89-92, 79 Stat. 282 (1965) 9

Federal Food, Drug, and Cosmetic Act,
21 U.S.C. § 301-395 ..... *passim*

National Traffic and Motor Vehicle Safety Act of 1966,
Pub. L. No. 89-563, 80 Stat. 718 (1966),
49 U.S.C. §§ 30101-30169 2

Public Health Cigarette Smoking Act of 1969,
Pub. L. 91-222, 84 Stat. 87 (1969) 9

15 U.S.C. § 1334(b) 9

21 U.S.C. § 360h(d) 4, 14

21 U.S.C. § 360k(a) ..... *passim*

28 U.S.C. § 1652 13

49 U.S.C. § 30103(b)(1) 3

TABLE OF AUTHORITIES - Continued

	Pages
49 U.S.C. § 30103(e)	3
49 U.S.C. § 30111(a)	2
S. Ct. R. 37.3(a)	1
Other Authorities	
G. Calabresi, *A Common Law for the Age of Statutes* (1982)	11
M. Eisenberg, *The Nature of the Common Law* (1988)	11
H.R. Rep. No. 1776, 89th Cong., 2d Sess. 17 (1966)	2
S. Rep. No. 1301, 89th Cong., 2d Sess. 12, U.S. Code Cong. & Ad. News 2709 (1966)	2

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On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF AMICUS CURIAE GENERAL MOTORS CORPORATION IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*

General Motors Corporation ("General Motors") is the world's largest manufacturer of automobiles.[1]

Prior to 1966, the American automobile industry was regulated primarily by an uneven combination of state common

[1] Pursuant to Rule 37.3(a) of this Court, both petitioner and respondents have consented to General Motors Corporation's filing of this brief as *amicus curiae*. Letters evidencing such consent are on file in the Clerk's office.

law and state legislative enactments that differed widely from one state to another. Often the courts led the way by developing and applying common law principles. These substantive principles, in turn, were sometimes later codified or revised by the state legislatures when they took the initiative to resolve particular problems with the common law or address particular concerns. The result was a haphazard patchwork of state-law regulation of the automobile under the common law and under statutory and regulatory provisions.

In 1966, however, Congress determined that, given the "centralized, mass production, high volume character of the motor vehicle manufacturing industry in the United States," the country needed "strong and adequately enforced" federal motor vehicle safety standards that were "*uniform* throughout the country." S. Rep. No. 1301, 89th Cong., 2d Sess. 12, *reprinted in* 1966 U.S. Code Cong. & Ad. News 2709, 2720 (emphasis added); *see* H.R. Rep. No. 1776, 89th Cong., 2d Sess. 17 (1966). Accordingly, Congress enacted the National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 718 (1966), 49 U.S.C. §§ 30101-30169 (the "Safety Act"), which directed the Department of Transportation, through the National Highway Traffic Safety Administration ("NHTSA"), to develop and issue federal motor vehicle safety standards that are "practicable," "meet the need for motor vehicle safety," and apply uniformly throughout the country. 49 U.S.C. § 30111(a).

The structure of the preemption provisions in the Safety Act is similar (though not identical) to those in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-395 (the "FDCA"), the statute under review in this case. Specifically, the Safety Act contains an express preemption clause that provides:

> When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or

> motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter. 49 U.S.C. § 30103(b)(1).

Moreover, similar to the FDCA, the Safety Act also contains what has sometimes been referred to as a "savings" clause. That provision states as follows:

> Compliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law. 49 U.S.C. § 30103(e).

The similarity in structure of the statutory provisions concerning preemption contained in the FDCA and the Safety Act, *compare infra* at 4-5, makes the resolution of certain issues in this case potentially relevant to similar issues that have arisen under the Safety Act. In particular, *amicus* General Motors has an interest in the resolution of two questions that have arisen in this case, which we address here: *First*, does an express preemption provision that broadly preempts any different state-law "requirement[s]" (the FDCA) or "standard[s]" (the Safety Act) preempt state common law damages actions that would, if allowed, set requirements or standards that differ from the applicable federal requirements or standards? *Second*, does the mere inclusion by Congress of a so-called "savings clause" for common law liability afford state common law damages actions a *blanket* exemption from an express preemption provision that, by its plain terms, covers the state common law?

As the resolution of these questions in the context of the FDCA is relevant to litigation under the Safety Act, General Motors has an interest in the Court's analysis and resolution of the issues presented in this case.[2]

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[2] We note that the case before the Court has been litigated solely on grounds of express preemption, *see* Pet. App. 10a n.5, and accordingly any

(continued...)

INTRODUCTION

The FDCA contains two provisions that are most germane to the preemption issues presented in this case.

First, the FDCA contains an "express preemption clause," 21 U.S.C. § 360k(a), which states as follows:

> Except as provided in subsection (b) of this section [not relevant here], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Second, the FDCA also contains a so-called "savings clause," 21 U.S.C. § 360h(d), which states as follows:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action

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[2](...continued)
determination of implied conflict preemption under the FDCA and its implementing regulations is not at issue at this juncture. As under the Safety Act, however, implied conflict preemption will arise in appropriate cases as the courts confront state common law claims that directly conflict with the statutory and regulatory scheme. *See, e.g.*, Medtronic Br. at 46 n.24; Lohrs' Br. at 23 n.6.

> of any remedy provided him under such order shall be taken into account.

This provision is found in Subchapter V of the FDCA, which specifically applies to drugs and medical devices.

A harmonious and sensible construction of these two provisions goes a long way toward resolving the preemption issues raised in this case, and is also relevant generally to basic preemption issues that arise under a number of other federal regulatory statutes, including the Safety Act.

In harmonizing these provisions, the Court of Appeals made four determinations that are germane to the issues addressed by *amicus* General Motors:

First, the Court of Appeals held that reference in section 360k(a), the express preemption clause, to state "requirement[s]" covered not only state statutory law and administrative regulations, but also requirements that are imposed by state common law damages actions. Pet. 11a.

Second, it held that the existence of the so-called "savings clause" in the FDCA did not alter its conclusion that section 360k(a) covered "requirement[s]" imposed by common law damages actions, because the savings clause could be construed in any of several different ways without concluding that it was intended to exempt *all* common law damages actions from the preemptive force of section 360k(a), and that in any event a general savings clause "cannot supersede the specific preemption provision." Pet. 12a.

Third, the Court of Appeals therefore held that whether specific state requirements or standards were preempted under the FDCA demanded "a claim-by-claim inquiry" into whether each individual state claim would impose requirements that "are 'different from or in addition to' and 'relate to any matter' included in a specific [federal] requirement." Pet. 22a-23a (quoting 21 U.S.C. § 360k(a)).

Finally, the Court of Appeals held that its claim-by-claim preemption analysis must be guided by "the presumptions against preemption," and that "in a close case the presumptions tip our statutory interpretation against preemption." Pet. 9a.

Amicus General Motors respectfully submits that each of these conclusions, *except the last one* (concerning the purported presumptions against preemption) is correct, and, for the reasons addressed here, the Court should so hold in deciding this case.

SUMMARY OF ARGUMENT

1. The express preemption clause in the FDCA -- section 360k(a) -- prohibits each state from establishing or continuing in effect any requirement that is different from, or in addition to, any FDCA "requirement" that applies to the same medical device, and that relates to its safety, effectiveness, or any other matter governed by federal law. The Lohrs argue that state common law damages actions enjoy a *blanket* immunity from case-by-case preemption analysis because state common law is not a "requirement" within the meaning of section 360k(a).

The Lohrs' argument is plainly wrong for a number of reasons. First, the Court has already rejected their argument in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), holding that a term in an express preemption clause such as "requirement[s]" sweeps broadly and easily encompasses state common law. Second, even if the issue were not foreclosed, the Lohrs' argument ignores that state common law can set "requirements" regulating private conduct as much as state positive law. Third, the Lohrs' argument rests on the bizarre assumption that Congress intended that a single state jury -- an *ad hoc* collection of citizens assembled to hear one case -- should have more power to regulate private conduct in a manner different from the federal government than a state's duly elected and appointed officials. Moreover, the Lohrs'

contorted linguistic argument why "requirement[s]" does not cover state common law, if accepted, would undermine cases as basic as *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938).

2. The Court should also reject the Lohrs' extreme position that the mere existence of a so-called general "savings" clause in a federal statute demonstrates that the common law is beyond the reach of an express preemption provision which would otherwise cover the common law. The Court has expressly held in prior cases that a general savings clause cannot control the obvious thrust of an express preemption clause. Indeed, the most sensible reading of the savings clause is as a general admonition that the mere enactment of the federal statutory scheme should not be understood to "occupy the field" so as to displace any and all state regulation at the outset of the regulatory regime. Under such a reading, state common law is neither completely displaced, nor completely immunized from express preemption. Instead, determination of the extent to which state common law is expressly preempted must proceed on a claim-by-claim basis, and will depend in large part on the nature of the federal regulations and standards that are established through the regulatory process. That is precisely what the Court of Appeals correctly held in this case.

3. Finally, in conducting its claim-by-claim determination of whether the Lohrs' common law claims are preempted, the Court of Appeals erred in relying on a so-called "presumption against preemption" as a means of tipping the balance in a close case. This Court's prior statements concerning a presumption against preemption are best understood as limited to cases where it is claimed that state law is displaced in its entirety because Congress has "occupied the field." A presumption against preemption is appropriate in such cases because it is consistent with basic tenets of federalism and of limited congressional powers. However, such a presumption has no place in cases of express preemption, where the central issue is whether particular

statutory or regulatory requirements enacted or authorized by Congress should be understood to displace state law. In such cases, the question of preemption is merely a question of straightforward statutory construction, and there should be no freestanding presumption that Congress has exercised its enumerated powers in any manner other than that which is most consistent with the plain meaning and effect of the specific preemptive provisions at issue. And, of course, with respect to implied conflict preemption, a conflicting state law is preempted by direct operation of the Supremacy Clause, and there is no presumption against the application of the Supremacy Clause.

ARGUMENT

I. THE FDCA'S EXPRESS PREEMPTION CLAUSE APPLIES TO "REQUIREMENTS" IMPOSED BY STATE COMMON LAW AS WELL AS THOSE IMPOSED BY STATE LEGISLATIVE AND REGULATORY ENACTMENTS.

The express preemption clause in the FDCA prohibits each state from "establish[ing] or continu[ing] in effect" any "requirement" that is "different from, or in addition to, any requirement" that the FDCA applies to the same medical device, and which relates to its safety, effectiveness, or any other matter governed by federal law. 21 U.S.C. § 360k(a). The Lohrs contend that "requirement[s]" means "only positive state law, not common-law tort claims," Lohrs' Br. at 17, and therefore that *all* common law damages actions -- regardless of whether they set requirements or standards that differ from a federal requirement that is directly applicable -- are immune from a claim-by-claim determination of whether they are preempted under section 360k(a). This extreme position is plainly wrong for a number of reasons.

First, in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Court rejected the very argument advanced by the Lohrs, holding that the inclusion of the term "requirements" in

an express preemption provision plainly covers requirements set by common law damages actions. In *Cipollone*, the Court was obliged to construe the express preemption provisions contained in two successive federal statutes -- the Federal Cigarette Labeling and Advertising Act, Pub. L. 89-92, 79 Stat. 282 (1965), and the Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87 (1969). The Court determined that in the preemption provision in the 1965 Act, "Congress spoke precisely and narrowly: 'No statement relating to smoking and health shall be required in the advertising of [properly labeled] cigarettes.'" *Cipollone*, 505 U.S. at 518 (quoting section 5(b) of the 1965 Act). The Court noted that this language was consistent with "the continued vitality of state common law damages actions," and thus was "best read as having superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels." *Id.* at 518-19.

The Court held, however, that Congress changed the situation dramatically by enacting the "much broader" express preemption clause contained in the 1969 Act. 505 U.S. at 520. That provision introduced new constraints upon all manner of requirements, duties, and standards imposed under state law by stating that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes" that are labeled as required under federal law. 15 U.S.C. § 1334(b). Based on this language -- particularly the reference to "requirement[s] or prohibition[s] . . . imposed under State law" -- the Court held that common law actions were within the coverage of the express preemption provision contained in the 1969 Act. 505 U.S. at 520-24.[3]

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[3] The plurality opinion on this point actually speaks for the majority, for it is reinforced by the express agreement of Justices Scalia and Thomas. *See* 505 U.S. at 548-49 (Scalia, J., concurring and dissenting in part).

In *Cipollone*, the Court specifically rejected the Lohrs' linguistic argument designed to limit the scope of the term "requirement" to exclude the effects of damage actions brought under state common law. The Court explicitly found this argument to be "at odds both with the plain words of the 1969 Act and with the general understanding of common law damages actions." 505 U.S. at 521. In a key passage that squarely defeats the Lohrs' contentions to the contrary in this case, the Court stated: "The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." *Id.* Even though there was some evidence in the legislative history suggesting that Congress "was primarily concerned with positive enactments by States and localities," the Court was emphatic that "the language of the Act *plainly* reaches beyond such enactments." *Id.* (emphasis added).[4]

Second, even if the Lohrs' argument were not squarely foreclosed by *Cipollone*, it is still plainly wrong because it ignores the ordinary interrelations between the substantive principles of the common law and statutory law in regulating the health, safety, and welfare of citizens in each state. Again, the Court discussed this point in *Cipollone*, and pointed out that "common law damage actions of the sort raised by petitioner are premised on the existence of a legal duty and it is difficult to say that such actions do not impose 'requirements or prohibitions,'" for "it is the essence of the common law to enforce duties that are either affirmative requirements or negative prohibitions." 505 U.S. at 522.

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[4] In Justice Scalia's separate opinion, which was joined by Justice Thomas, he expressly agreed that the broader language of the 1969 Act "plainly reaches beyond [positive] enactments," and that "general tort-law duties" can impose requirements or prohibitions within the meaning of the 1969 Act. *See* 505 U.S. at 548-49 (Scalia, J., concurring and dissenting in part).

In this regard, it simply does not matter whether the source of the substantive component of that state law is the state's legislature, regulatory agencies, or courts. It likewise does not matter whether the *remedy* used to enforce the substantive component of that law is the payment of damages to private parties rather than the payment of fines to the government or some other enforcement mechanism, and the Lohrs' arguments to the contrary, *see, e.g.*, Lohrs' Br. at 20, simply miss the mark. "[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *San Diego Bldg. Trades Council, Millmen's Union, Local 2020 v. Garmon*, 359 U.S. 236, 247 (1959).

The intricate relationship between state common law and state statutory and administrative law in regulating private conduct, and the extent to which they are inherently interwoven, is well known and readily demonstrated. Earlier in this century, the courts typically led the way by applying and developing common law principles to regulate the private sector. The requirements, obligations, and standards imposed in accordance with these principles, in turn, were eventually codified and at times modified by state legislatures when they took the initiative to address particular problems and concerns. On occasion, legislatures have enacted regulatory statutes conferring administrative authority on government agencies to take more initiative in regulating private conduct, while still retaining the common law to fill many of the remaining gaps in coverage between these positive enactments. In many instances, the further interaction of state legislation and state common law adjudication becomes intricate and complex, with legislative or regulatory enactments sometimes used to supply the duty of care underlying private damage actions. *See generally* M. Eisenberg, *The Nature of the Common Law*, (1988); G. Calabresi, *A Common Law for the Age of Statutes* (1982).

At the state level, therefore, it is undeniable that the common law forms an integral, and interwoven, part of the comprehensive regulation of private conduct. Taken in combination with statutory and regulatory enactments, the common law imposes a continual procession of "requirements," obligations, prohibitions, and standards that are designed to influence and regulate the actions of businesses and individual citizens. Any reading of such terms to erect a putative distinction between the common law and positive law in this respect would be fundamentally misguided.

Third, the Lohrs' argument rests on the bizarre assumption that Congress intended that an *ad hoc* collection of state citizens assembled to hear one civil case -- a jury -- should have greater power to set standards that differ from uniform federal requirements than state officials acting through the careful, deliberative processes established in the legislative and administrative spheres. Such a result would be a perverse undermining of the democratic process. Moreover, the Lohrs' argument would suggest that the FDCA would preempt a state statute or administrative regulation imposing a $100 fine for engaging in particular conduct, but would not preempt a jury in state court from imposing a million-dollar damage award for engaging in the very same conduct. The Court should not assume that Congress intended such a strange result unless it clearly so provided. Nothing in the language of section 360k(a) requires that upside-down worldview. Indeed, for the reasons stated above, section 360k(a) plainly contemplates that state juries, just like state administrative and legislative officials, set "requirement[s]" that must be measured against federal action to determine if they are preempted.

Against all of this, the Lohrs offer only a far-fetched linguistic argument to support their assertion that state "requirements" includes only positive enactments and not those requirements imposed under state common law. They observe that the same term -- "requirement" -- is used in 21 U.S.C. § 360k(a) to refer *both* to federal requirements and to state

requirements. Yet because the federal "requirements" referred to are only those imposed by statute or administrative regulation (for there is no federal common law in this regard), they argue that the state "requirements" referenced must also be only those imposed by state statutes or regulations. Lohrs' Br. at 17-19.

This argument is untenable. The term "requirement" as used in 21 U.S.C. § 360k(a) refers to those prohibitions, standards, and obligations imposed *by law*, whether that law is state or federal. That there may be a variety of *sources* of law from which such requirements are derived, and that those sources of law may not mirror one another in every respect at the state and federal level is quite beside the point.

Indeed, the Lohrs' argument on this point is so plainly wrong that, if accepted here, its logic would partially overrule *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938). The very same argument that the Lohrs put forward with respect to the use of the term "requirement" in section 360k(a) would apply equally well to the term "laws" in the Rules of Decision Act, 28 U.S.C. § 1652. The Rules of Decision Act requires a federal court to apply "[t]he laws of the several states" as the rules of decisions in civil actions not arising under federal law. Applying the logic of the Lohrs' argument, because the Supremacy Clause refers also to "the *Laws* of the United States," U.S. Const., art. VI, cl. 2 (emphasis added), and because there is no general common law of the United States, then the phrase "the laws of the several states" should be limited to the *positive* law of the several states, thereby excluding state common law as the governing rules of decision in federal courts. Adoption of the Lohrs' argument thus would have the pernicious consequence of upsetting the entire basis for the *Erie* doctrine.

It is, therefore, not surprising that, in *Cipollone*, the Court rejected the parallel argument that the phrase "State law" included *only* state statutes and regulations, but not state common law. *See* 505 U.S. at 522-23; *see also id.* at 549 (Scalia, J., concurring and dissenting in part) (agreeing that the

phrase "State law" used in the 1969 Act "embraces state common law"). The Court recognized that this argument was flatly irreconcilable with its longstanding construction of essentially the same language in the Rules of Decision Act. *See Erie*, 304 U.S. at 77-78. Indicating no desire to revisit the controversial battles fought over many decades that led up to the Court's historic decision in *Erie* to overrule the contrary interpretation of the Rules of Decision Act that had been adopted much earlier in *Swift v. Tyson*, 41 U.S. (16 Pet.) 1 (1842), the Court simply noted that "we have recognized the phrase 'state law' to include common law as well as statutes and regulations." *Cipollone*, 505 U.S. at 522. For all the same reasons, the Lohrs' attempt to limit the term "requirement[s]" to state positive law must fail.

II. THE ORDINARY PURPOSE OF A SAVINGS CLAUSE IS TO AVOID ANY INFERENCE OF "FIELD" PREEMPTION, AND IN ANY EVENT ITS GENERAL LANGUAGE DOES NOT CONTROL SPECIFIC PROVISIONS OF AN EXPRESS PREEMPTION CLAUSE.

The Medical Device Amendments ("MDA") to the FDCA also contain a so-called "savings clause" in section 360h(d). That section states that "[c]ompliance with an order [under the MDA] shall not relieve any person from liability under Federal or State law." *Id.* The Court of Appeals held that "[t]he existence of a savings clause within the MDA cannot alter th[e] conclusion" that the FDCA's express preemption provision covers state common law damages actions as well as state statutes and regulations. Pet. App. 12a. The Lohrs disagree, arguing that the existence of the savings clause in section 360h(d) "demonstrate[s] that the common law is beyond the reach of section 360k(a)," which is the express preemption clause. Lohrs' Br. at 12; *see also id.* at 27-28.

Once again, the Lohrs are mistaken. The most sensible reading of a savings clause like that in section 360h(d), especially in conjunction with an express preemption clause, is

that the savings clause is included merely to clarify that Congress disclaims any intention to preempt the common law *in its entirety* (*i.e.*, to "occupy the field"), but rather intends that preemption of common law claims should be determined on a claim-by-claim basis. The Lohrs' more extreme reading of the savings clause is incorrect for at least two reasons:

First, for the reasons already discussed, statutory terms denoting the scope of preemption, such as "requirements," "prohibitions," "standards," and "obligations," cannot be fairly read to include only positive enactments of law and not state common law. *See* Section I, *supra*. The Lohrs' reading of the savings clause would thus require the Court to restrict, and not respect, the plain meaning and reach of the broad terms Congress used in the express preemption clause.

Second, the Lohrs' suggestion that the existence of a savings clause should be read to immunize the common law from any possibility of express preemption would also lead to absurd consequences that Congress simply cannot be presumed to have intended. A simple example proves the point: Suppose that, in the course of approving a particular medical device to market under the FDCA's premarket approval application process, the FDA issues a regulation providing that the specific device at issue must be produced only with a certain component that is made of stainless steel, because stainless steel is more reliable and safer than other alternative materials. Is it conceivable that Congress could have meant its express prohibition of different state requirements not to reach a state common law damages action premised on the theory that the device was defectively designed because it was made of stainless steel instead of some other alternative material? Surely not. That would subordinate a specific federal decision to a conflicting state one. But that is the consequence of the Lohrs' argument that the existence of a savings clause somehow immunizes state common law from a claim-by-claim

determination of preemption under an express preemption clause.[5]

Amicus General Motors respectfully suggests that, rather than reading a savings clause as negating the plain meaning of an express preemption clause, thereby sanctioning an array of absurd results that Congress simply could not have intended, the Court should read the savings clause as merely clarifying that Congress did not intend to displace *all* state common law (*i.e.*, to occupy the field) by enacting the federal regulatory scheme, but rather intended that preemption of state common law should be determined on a claim-by-claim basis according to the terms of the express preemption clause.

This construction of the two provisions is consistent with the Court's prior cases, which have repeatedly held that a savings clause is merely meant to establish that Congress did not intend field preemption. *See, e.g., John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 114 S. Ct. 517, 526 (1993) (the consequence of a savings clause is that state law "generally is not displaced, but where [that] law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress, federal preemption occurs") (internal quotes omitted); *Pennsylvania R.R. v. Puritan Coal Mining Co.*, 237 U.S. 121, 130-32 (1915) (savings clause was included in Interstate Commerce Act to refute the claim "that, Congress having entered the field, the whole subject of liability of carrier to shippers in interstate commerce had been withdrawn from the jurisdiction of the state courts," without regard to whether any "administrative question" was posed under the federal law).

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[5] Of course, such a conflicting state requirement would be preempted by direct operation of the Supremacy Clause in any event, applying standard principles of implied conflict preemption. The case before the Court, however, has been litigated solely on grounds of express preemption. *See* note 2, *supra*.

The reading we suggest is also consistent with the Court's prior cases which have consistently held that the general language of a savings clause cannot control or limit the main thrust of an express preemption clause. *See, e.g., Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 385 (1992) ("general 'remedies' saving clause cannot be allowed to supersede the specific substantive pre-emption provision"). More generally, the Court has routinely given savings clauses a narrow reading in order to render them consistent with the preemptive thrust of the statute as a whole. *See, e.g., Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51-52 (1987) (saving clause given narrow reading after the Court looked "to the provisions of the whole law, and to its object and policy").[6]

Thus, when Congress provides, as it often does, both that (i) any state requirement or standard that differs from an established federal requirement or standard is preempted, and that (ii) compliance with federal requirements is not meant to relieve a person of liability under the common law, the appropriate preemption inquiry with respect to a common law damages action is a claim-by-claim determination of the effect of allowing any such damages action to proceed. Where the common law damages action would have the effect of either setting a requirement or standard that differs from a federal

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[6] Indeed, even where the statute contains no express preemption clause at all, or where principles of implied conflict preemption are at issue, the general language of a savings clause cannot be read to save state common law claims that conflict with the overall purposes of the federal statutory scheme, which are preempted "by direct operation of the Supremacy Clause." *Brown v. Hotel & Restaurant Employees and Bartenders Int'l Union*, 468 U.S. 491, 501 (1984); *see also International Paper Co. v. Ouellette*, 479 U.S. 481, 493-94 (1987) (saving clause given narrow reading because "we do not believe Congress intended to undermine this carefully drawn statute through a general saving clause"); *Texas & Pacific Ry. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 446 (1907) (saving clause "cannot in reason be construed as continuing in shippers a common-law right, the continued existence of which would be absolutely inconsistent with the provisions of the act. In other words, the act cannot be held to destroy itself.").

requirement or standard already in place (express preemption) or otherwise conflicting with or undermining the main thrust of the federal statutory or regulatory scheme (implied preemption), *then and then alone* should the courts hold it to be preempted.

This approach -- which is essentially that followed by the Court of Appeals in this case -- rejects the polar extremes of either immunizing state law entirely from preemption or automatically displacing it in its entirety. Rather, this sensible approach would preempt state common law damages claims *only* to the extent that the effect of such claims would be to impose a requirement or set a standard that differs from a requirement or standard that is already in place under federal law. Accordingly, preemption of state common law claims would depend, in large part, on the specific action taken by the agency charged with enforcing the applicable federal statutory scheme. Only where Congress or the agency has imposed a federal requirement or standard will the state common law be prevented from operating in such a fashion as to impose a different requirement or standard. And determination of the preemptive effects of a particular federal requirement imposed by statute or regulation must be determined by the courts, to whom the authority is delegated to make such determinations in applying the Supremacy Clause. *Cf. Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-50 (1990) (determination of whether a statute affords a private right of action is matter to be established by the judiciary rather than the implementing agency).

This is, we suggest, exactly how preemption should be understood to operate in the modern administrative state in areas of dual federal-state regulation. In enacting the general statutory scheme, Congress cannot know for sure exactly which state laws, requirements or standards should be preempted where Congress leaves it to the relevant federal administrative agency to determine which federal regulations to establish. Thus, Congress usually enacts a general provision (in an

express preemption clause) that state laws which differ from federal "requirements" or "standards" -- whatever they may turn out to be -- will be preempted, but also provides (in a savings clause) that the mere enactment of the federal law should not be understood to displace state law in its entirety. State law is thus neither completely immunized nor totally displaced. Rather, the scope of federal preemption will turn in large measure on what the federal agency does in implementing the statute. If the agency decides to issue a federal regulation to govern some aspect of the performance of the product at issue, then different state requirements or standards as to that same aspect of performance -- whether they be imposed through statutory or common law -- are preempted. But otherwise, state statutory and common law can continue to operate in the same realm alongside federal law, provided they do not otherwise conflict with or undermine the federal regulatory scheme.

In short, we respectfully suggest that the Court should avail itself of the opportunity in this case to reject explicitly the Lohrs' extreme position that the mere existence of a savings clause "demonstrates that the common law is beyond the reach of [an express preemption clause such as] section 360k(a)," Lohrs' Br. at 12, where the plain terms of that express preemption clause are broad enough to cover state common law. Instead, the Court should reiterate that a savings clause should be read in harmony with an express preemption clause, not in derogation of it.

III. PREEMPTION ISSUES ARE MATTERS OF PURE STATUTORY CONSTRUCTION AND THUS ARE NOT GOVERNED BY THE ESTABLISHED PRESUMPTION AGAINST "OCCUPY THE FIELD" PREEMPTION.

Finally, in conducting its claim-by-claim determination of whether the Lohrs' common law claims were preempted, the Court of Appeals expressly held that "in a close case the

presumptions [against preemption] tip our statutory interpretation against preemption." Pet. App. 9a.

Amicus General Motors respectfully suggests that the Court of Appeals was wrong to rely in any way on a purported presumption against preemption in a case, such as this one, that does not involve field preemption. Rather, in our view, this Court's prior statements concerning a presumption against preemption should be read to express its appropriate reluctance to infer that federal law has entirely "occupied the field" and thus is intended to displace *all* state law in a particular area. To the extent that the lower courts, such as the Court of Appeals in this case, have interpreted this Court's prior cases as endorsing a presumption against enforcing the statutory instructions about preemption contained in an express preemption clause, we believe they have erred. The Court should therefore clarify in this case that such a presumption has no place in interpreting the scope of an express preemption clause, or the effect of any other federal statute or regulation that, by its own terms, expressly displaces state law.

The first several cases in which the Court discussed a presumption against preemption were all cases that addressed "field preemption." *See, e.g., Reid v. Colorado*, 187 U.S. 137 (1902); *Savage v. Jones*, 225 U.S. 501 (1912); *Napier v. Atlantic Coast Line R.R.*, 272 U.S. 605 (1926). In such cases, the preemption issue turned on whether Congress intended for federal action to occupy an entire field of regulatory authority, thus ousting the states from exercising any police power at all in that same area. In the circumstances of such a claim, a general presumption against any such sweeping federal displacement of state law is indeed compatible with basic tenets of federalism, because it limits the displacement of state governmental authority based on generalized inferences that

are not anchored in any specific statutory language. *See, e.g., Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).[7]

Putting the settled principle of a presumption against broad "field" preemption to one side, however, the same considerations do not come into play in those cases where preemption issues are framed more narrowly by the comparison of express statutory or regulatory language contained in federal law to specific requirements, obligations, or standards imposed under state law. In such cases, these difficult preemption issues are quintessentially matters of statutory interpretation, which thus are not properly subject to any presumptions at all. *See, e.g., English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978); *cf. Cipollone*, 505 U.S. at 545 (Scalia, J., concurring and dissenting in part) ("The ultimate question in each case, as we have framed the inquiry, is one of Congress' intent, as revealed by the text, structure, purposes, and subject matter of the statutes involved.").

It is important to recognize that the preemption issues raised by particular statutes do not raise any *constitutional* questions about whether federal law can or should displace state law, for any such questions are directly answered by the terms of the Supremacy Clause. There is, quite simply, no presumption against Congress' explicit exercise of its enumerated powers. Thus, preemption issues involving the construction and application of particular statutes or regulations -- as opposed to the more generalized issue of whether Congress has intended to "occupy the field" and thus eliminate *all* state regulatory power -- do not afford the proper occasion for invoking any constitutional presumption against

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[7] It is also particularly inappropriate for the courts to invoke cases involving constitutional "clear statement" rules, such as *Gregory v. Ashcroft*, 501 U.S. 452 (1991) (Tenth Amendment), and *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234 (1985) (Eleventh Amendment), as supposed authority for such a presumption against preemption in ordinary statutory or regulatory cases.

the displacement of particular aspects of state law by the provisions of federal law. *Cf. Cipollone*, 505 U.S. at 545 (Scalia, J., concurring and dissenting in part) (any preliminary presumption "dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself, and the only remaining question is what the scope of that pre-emption is meant to be"). Instead, the proper rule of construction once again should be grounded in the basic "assumption that the ordinary meaning of [the statutory] language accurately expresses the legislative purpose." *Morales*, 504 U.S. at 383 (quoting *FMC Corp. v. Holliday*, 498 U.S. 52, 57 (1990)).

It is particularly important for the Court to make clear to the lower courts that any presumption against preemption is limited to so-called "field" preemption, but does not otherwise apply to limit the plain and natural scope of an express preemption clause.[8] The dangers in speaking in terms of overarching "presumptions" are perhaps not evident in the Court's own decisions, where it is recognized that the proper resolution of preemption issues requires carefully working through all of the relevant statutory and regulatory language before reaching a conclusion. In the lower courts, however, casual invocation of supposed "presumptions" at times becomes a substitute for hard legal analysis. *Compare Tebbetts v. Ford Motor Co.*, 665 A.2d 345, 346-48 (N.H. 1995) (invoking presumption to justify finding of no express preemption, and deducing from that an intention to foreclose implied conflict preemption analysis), *cert. denied*, 116 S. Ct. 773, *reh'g denied*, 1996 WL 77746 (1996) *with Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995) (applying plain

[8] And, of course, with respect to implied conflict preemption, presumptions are utterly irrelevant because whenever state law conflicts with a federal statute or regulation, the conflicting state requirement is preempted "by direct operation of the Supremacy Clause." *Brown*, 468 U.S. at 501; *see also Cipollone*, 505 U.S. at 516 ("state law that conflicts with federal law is without effect").

language of preemption clause with no presumption, and then undertaking implied conflict preemption analysis). In this manner, the intended thumb on the scale often is transformed into a much more substantial weight, which exerts a disproportionate influence that skews or even short-circuits any meaningful judicial inquiry directed at the proper objective of divining congressional intent.

CONCLUSION

For the foregoing reasons, as well as those set forth in petitioner's brief, the decision below should be reversed in part and the case remanded for further proceedings in accordance with this Court's opinion.

Respectfully submitted,

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OCTOBER TERM, 1995

MEDTRONIC, INC,
Petitioner/Cross-Respondent,

vs.

LORA LOHR AND MICHAEL LOHR,
Respondent/Cross-Petitioners.

On Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

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39 pp

TABLE OF CONTENTS

IDENTITY AND INTEREST OF AMICUS CURIAE 1
SUMMARY OF ARGUMENT 2
ARGUMENT 4
I. TORT LIABILITY AND ADMINISTRATIVE REGULATION ARE RADICALLY DIFFERENT SAFEGUARDS OF PRODUCT SAFETY 5
A. Tort Liability Creates Market Incentives for Safety, While Regulation Relies on Direct Governmental Mandates. 5
B. This Court Has Consistently Held That Preemption Of State Regulation Does Not Necessarily Include The Indirect Effects Of Tort Liability. 7
II. COURTS MAY NOT FIND PREEMPTION OF STATE TORT REMEDIES UNLESS CONGRESS HAS CLEARLY AND UNAMBIGUOUSLY SO INTENDED. 10
A. Preemption of State Judicial Remedies Must Be Established by Clear and Unambiguous Statement of Congressional Intent to Protect State Sovereignty Guaranteed by the Tenth Amendment. 10
1. Regard for federalism requires a strong presumption against preemption of state tort law in the absence of clear and unambiguous Congressional intent. 10
2. Preemption of state tort remedies is an intrusion upon

fundamental rights historically safeguarded by the states. 11
3. Requiring Congress to speak plainly when preempting state law protects state sovereignty. 12
B. Abolition of Common Law Remedies Without Alternative Means For Redress Is Constitutionally Suspect. 14

III. THE PLAIN TEXT OF THE MDA DOES NOT REFLECT A CLEAR AND MANIFEST INTENT TO PREEMPT STATE TORT law. 16
A. The Term "Requirement" Does Not Clearly And Unambiguously Include Product Liability. 16

B. The Plain Meaning Of The MDA Reflects Congressional Intent To Preempt State Administrative Regulation, Not Product Liability Actions. 17
1. The text of §360k(a) indicates that congress intended requirement to include only positive law. 17
2. A jury verdict does not establish a "requirement" with respect to a device. 18
3. Product liability awards do not constitute a requirement established by the State. 20
4. 360k(b) indicates that Congress intended to preempt only positive law. 21

5. Section 360h(d) Reflects Congressional Intent To Preserve State Tort Actions 21
C. The Court's Decision in Cipollone Does Not Require that State Court Remedies Be Preempted Under the MDA. 22
1. Cipollone decision does not define "requirement" to include tort jury verdicts. 22
2. Garmon does not support preemption. 23

IV. THE LEGISLATIVE BACKGROUND OF MDA DOES NOT INDICATE CONGRESSIONAL INTENT TO PREEMPT PRODUCT LIABILITY ACTIONS. 24
A. Congress Intended To Make Regulation Of Devices More Consistent With Regulation Of Drugs Under The Parent Statute, Which Does Not Preempt Tort Law. 25
B. If Congress Intended To Eliminate Products Liability, It Would Have Done So Explicitly. 25

C. Congress Intended § 360k(a) To Apply to State Administrative Regulation. 26

V. THE FDA DOES NOT INTERPRET THE MDA AS PREEMPTING PRODUCT LIABILITY ACTIONS. 27

CONCLUSION 30

TABLE OF AUTHORITIES

Cases

Abbot v. American Cyanamid Co., 844 F.2d 1108 (4th Cir. 1988) *14, 25*
Atascadero State Hospital v. Scanlon, 473 U.S. 234 (1985) 11
Bravman v. Baxter Healthcare Corp., 842 F. Supp. 747 (S.D.N.Y. 1994) 27, 26
Brown v. Hotel & Restaurant Employees & Bartenders International Union Local 54, 468 U.S. 491 (1984) 24
Burke v. Dow Chemical Co., 797 F. Supp. 1128 (E.D.N.Y. 1992) 20
Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989) 21, 27
Carlisle v. Philip Morris, Inc., 805 S.W.2d 498 (Tex. App. 1991) *12*
Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 5, 9, 11, 16, 17, 20, 22, 23, 24
Consumer Federation of America v. Upjohn, 346 A.2d 725 (D.C. App. 1975) *25*
Covey v. Surgidev Corp., 815 F.Supp. 1089 (N.D. Ohio 1993) 19
CSX Transp. Inc. v. Easterwood, 113 S. Ct. 1732 (1993) 11
Deemer v. A.H. Robins Co., No. C-30649 (Kan. Dist. Ct., Feb. 7, 1975) 26
Duke Power Co. v. Carolina Environmental Study Group, 438 U.S. 59 (1978) 15
English v. General Electric Co., 496 U.S. 72 (1990) 9, 24
Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir. 1984) *20*
Fitzgerald v. Mallinckrodt, Inc., 681 F. Supp. 404 (E.D. Mich. 1987) 18
Garcia v. San Antonio Metropolitan Transit Authority. 469 U.S. 528 (1985) 12

Goodyear Atomic Corp. v. Miller, 486 U.S. 174 (1988) *9*
Gregory v. Ashcroft, 111 S. Ct. 2395 (1991) *13*
Hawaiian Airlines, Inc. v. Norris, 114 S. Ct. 2239 (1994) 17
Hillsborough County v. Automated Medical Lab., Inc., 471 U.S 707, 714 (1985) 10, 28
Hunsaker v. Surgidev Corp., 818 F. Supp. 744 (M.D. Pa. 1992) 18
Hurley v. Lederle Laboratories, 863 F.2d 1173 (5th Cir. 1988) 25
Kansas Malpractice Victims Coalition v. Bell, 757 P.2d 251 (Kan. 1988) 12
Kennedy v Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) *4*
King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993) 19
Lucas v. United States, 757 S.W.2d 686 (Tex. 1988) 12
Lynn v. United Plant Guard Workers, 383 U.S. 53 (1966) 12
MacGillivray v, Lederle Laboratories, 667 F. Supp. 743 (D.N.M. 1987) 20
Marbury v. Madison, 5 U.S. (1 Cranch) 137 (1803) 15
Maryland v. Louisiana, 451 U.S. 725 (1981) 10
Michael v. Shiley, Inc., 46 F.3d 1316 (3rd Cir. 1995) 26
Milwaukee v. Illinois, 451 U.S. 304 (1981) 10
Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426 (C.D. Cal. 1994) 26
Missouri Pacific Ry. Co. v. Humes, 115 U.S. 512 (1885) 15
Moore v. Mobile Infirmary Assoc., 592 So. 2d 156 (Ala 1991) 12
Mulligan v. Pfizer, Inc., 1994 WL 158819 (S.D. Ohio, April 1, 1994) *22*
National League of Cities v. Usery, 426 U.S. 833 (1976) 12
New York Conference of Blue Cross v. Travelers Ins.,

115 S. Ct. 1671 (1995)..... *20*
New York v. United States, 112 S. Ct. 2408 (1992) 10
Pappas v. Upjohn Co., 926 F.2d 1019 (11th Cir. 1991) 21
Pilot Life Ins. Co. v. Dedeaux, 107 S. Ct. 1549 (1987)..... 9
PruneYard Shopping Center v. Robins, 447 U.S. 74 (1980) 16
Reeves v. Acromed Corp., 44 F.3d 300 (5th Cir. 1995)..... 19
Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947)..... *11*
San Diego Building Trades Council v. Garmon, 359 U.S. 236, 247 (1959)..... 23, 24
Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) 8
Smith v. Department of Insurance, 507 So. 2d 1080 (Fla. 1987)..... *12*
Sofie v. Fibreboard Corp., 771 P.2d 711 (Wash. 1989) 12
Taylor v. General Motors Corp., 875 F.2d 816, 824 (11th Cir. 1989)..... 21
Truxillo v. Ray-Ban, Div. of Bausch & Lomb, Inc., 1992 WL 209302 (E.D. La., Aug. 11, 1992) 22
United Construction Workers v. Laburnum Const. Co., 347 U.S. 656, 665 (1954) 14, 24
United States v. Rutherford, 442 U.S. 544 (1979) 28
Will v. Michigan Dept. of State Police, 491 U.S. 58 (1989) 11
Worm v. American Cyanamid Co., 970 F.2d 1301 (4th Cir. 1993)..... 21

Constitutions, Statutes, and Rules

21 C.F.R. 808.1(d)..... 28, 29
21 U.S.C.A. §§ 360c-360l (West Supp. 1994)..... 4
21 U.S.C. § 360h(d)..... 22
21 U.S.C. § 360k(a)..... passim
21 U.S.C. § 360k(b)..... 21

43 Fed. Reg. 18663 (May 2, 1978)..... 29
15 U.S.C. §1334 (Federal Cigarette Labeling and Advertising Act)..... 23

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976)..... 27
H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976)..... 26, 27
Hearings on S. 1944 Before a Subcommittee of the Committee on Commerce, U.S. Senate, 73rd Cong., 2d Sess. 400 (1933)..... 25
Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87 23
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IN THE

Supreme Court of the United States

October Term, 1995

Nos. 95-754, 95-886

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,
v.

LORA LOHR AND MICHAEL LOHR,
Respondent/Cross-Petitioners.

On Writ Of Certiorari to the United States Court Of Appeals For The Eleventh Circuit

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BRIEF OF AMICUS CURIAE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF THE CROSS-PETITIONERS

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ["ATLA"] is a voluntary national bar association of approximately 50,000 attorneys who primarily represent plaintiffs in personal injury, civil rights, and commercial law cases. Letters of consent of the parties have been filed with the Court.

ATLA views the increasing willingness of some federal courts to find preemption of common law tort remedies as an assault on the fundamental right of injured persons to legal redress. Elimination of product liability claims as preempted by the Medical Device Amendments of 1976 represents a

particularly egregious violation of this right because Congress clearly did not intend this result.

SUMMARY OF ARGUMENT

1. Preemption under the MDA of state liability law depends entirely upon the proposition that by expressly preempting state "requirements," Congress clearly intended to include both administrative regulations and products liability actions. In fact, regulation and tort liability have long been understood as fundamentally distinct means of promoting product safety. Indeed, they may be understood as polar opposites with respect to the feature of greatest importance to preemption -- the use of government power.

While administrative regulation operates by direct governmental mandates, product liability affects product safety by indirectly influencing marketplace incentives. By making the manufacturer of an unreasonably dangerous product responsible for the harm it causes, products liability encourages manufacturers to undertake cost-effective safety measures.

This Court's decisions have long recognized that federal preemption of direct government regulation by states does not necessarily include the indirect effect exerted by liability law. It is unlikely that Congress intended a radical departure from these settled principles.

2. This Court has consistently instructed that courts may not find preemption of state tort remedies in the absence of clear and unambiguous evidence that Congress so intended. The presumption is particularly strong against preemption of traditional state tort law where injured persons would be left without any remedy. The lower court, while reciting the formula of presumption, did not accord it the appropriate weight.

The presumption against preemption is not merely a rule of statutory construction. It is essential to safeguarding the role of the states in the federal system. The responsibility of

courts to require a clear statement of Congressional intent to preempt state law minimizes intrusions on state autonomy safeguarded in the Tenth Amendment by assuring that states are afforded the opportunity to influence federal law through representation in Congress.

The strong presumption against preemption where no alternative remedy is provided serves to avoid potential deprivation of substantive due process.

3. The term "requirement" in §360k(a) does not clearly and unambiguously include product liability law. For that reason alone, the Court should decline to find preemption.

The plain text of the statute indicates that Congress intended to preempt state positive law, not product liability actions.

Medtronic identifies product liability verdicts as the offending state "requirement" within §360k(a). However, a verdict for plaintiff in a products case requires only that the defendant pay compensation to the injured plaintiff. It does not require the defendant to take any action with respect to the product. The role of the jury is to find facts; verdicts do not "establish" a legal requirement. Nor is the jury, particularly the jury in a federal diversity case, a "state."

Nor does this Court's decision in *Cipollone* support preemption under the MDA. The central teaching of *Cipollone* is that the scope of an express preemption provision is governed by the language of the specific statute. *Cipollone* explicitly recognizes that preemption of state "requirements" does not necessarily eliminate state tort actions for damages. In addition, this Court's decision in *Garmon* does not address the crucial distinction in this case between direct governmental regulation and the indirect influence of tort awards.

4. The legislative history of the MDA confirms that Congress intended to preempt only positive state law. Congress was acutely aware of product liability lawsuits against device

manufacturers. If it intended to eliminate such actions, it would have done so explicitly.

5. The interpretation of the FDA as to the scope of preemption under the MDA is to be accorded substantial deference. The FDA has consistently maintained that §360k(a) does not eliminate product liability actions.

ARGUMENT

Amicus addresses this Court on a single dispositive issue in this case: Whether a product liability verdict is a state "requirement" expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C.A. §§ 360c-360l (West Supp. 1994) [hereinafter "MDA"]. For nearly two decades after Congress enacted the MDA to protect consumers from unsafe medical devices, people injured by defective medical devices were afforded legal remedy. At the same time, Congress repeatedly rejected "tort reform" proposals to limit the liability of manufacturers whose products comply with FDA regulations. Recently, a majority of federal courts of appeals have "discovered" Congress intended to eliminate product liability actions. Robert S. Adler and Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 941 (1994).

This dramatic reversal proceeds from a single proposition. The lower court, agreeing with the majority of U.S. courts of appeal, held that not only both positive law -- legislative and administrative regulation -- but also "common law actions are state requirements within the meaning of § 360k(a)." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 & n,7 (11th Cir. 1995); *contra Kennedy v Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995). This is also the basis for Medtronic's preemption argument to this Court. Brief For Petitioner Medtronic, Inc. ["Medtronic Brief"] at 37.

ATLA suggests that imputing this intent to Congress fails to recognize the fundamental distinction between administrative regulation and tort liability, fails to accord the proper weight to the presumption against preemption, and misapplies this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). In addition, this interpretation conflicts with both the legislative history of the MDA and the Food and Drug Administration's own authoritative interpretation.

I. TORT LIABILITY AND ADMINISTRATIVE REGULATION ARE RADICALLY DIFFERENT SAFEGUARDS OF PRODUCT SAFETY

A. Tort Liability Creates Market Incentives for Safety, While Regulation Relies on Direct Governmental Mandates.

Medtronic appears to view state positive law and common law as Siamese twins -- sufficiently equivalent methods of regulation that Congress would naturally intend to include both within the term "requirement." Medtronic Brief at 36-40. Similarly, Medtronic attributes to Congress a willingness to eliminate common-law remedies, relying on federal regulation as the sole safeguard against dangerous medical devices. *Id.* at 47-48. ATLA suggests that this presumed equivalence between regulation and common law is a radical departure from longstanding principles of product safety in this country.

The vast array of products, their complexity, and mass production and marketing have dramatically increased the potential for harm to consumers. Much of the thrust of product safety law in this century has been aimed at assuring products are reasonably safe when they enter the marketplace. Indeed, it was the primary goal of Congress in enacting the MDA to vest the FDA with authority to conduct premarket analysis of medical devices similar to the regime applied to drugs. For a detailed history of device regulation, see Gail H. Javitt, *I've Got You Under My Skin-And I Can't Get Redress: An Analysis Of Recent Case Law Addressing Preemption Of*

Manufacturer Liability For Class III Medical Devices, 49 Food & Drug L.J. 553 (1994).

Administrative regulation differs from liability in so many areas that they are often viewed as polar opposites. *See* American Law Institute, Reporters' Study: Enterprise Responsibility For Personal Injury vol I, 47-49 (1991); Teresa M. Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 12 J. Prod. Liab. 305 (1989); Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Studies 357 (1984). Of greatest importance for purposes of preemption analysis is the crucial difference in their use of the power of government.

State product liability law, in addition to providing compensation to wrongfully injured persons, also seeks to assure reasonable safety in products that enter the marketplace. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825 (1973). In his classic exposition, Judge Calabresi, contrasts governmental regulatory mandates, which he labels "specific deterrence," with the indirect influence of "general deterrence" exerted by tort law. Guido Calabresi, The Costs of Accidents 68-129 (1970).

Products liability is premised on the idea that the cost of harm caused by an unreasonably dangerous product should be borne by those who have placed it in the stream of commerce, who can spread those costs through the purchase price. Restatement (Second) of Torts §402A, comment c (1965). In the absence of liability, those costs fall on the injured consumer, who may be covered by insurance or government programs. Nonliability is, in effect, a subsidy to the makers of unsafe products, giving them an economic advantage over producers who have invested in safety. Calibresi, *supra*, at 70. Product liability forces manufacturers to "internalize" the cost of harm caused by unreasonably dangerous products, so that the purchase price of a product reflects its true social cost. The manufacturer can then determine the most cost-efficient

means of minimizing those costs. Where prevention of injury is cheaper than compensating the victims, the manufacturer will invest in safety. *See* William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 Yale L.J. 1099, 1119-20 (1960); Richard C. Ausness, *Compensation For Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 46 Wayne L. Rev. 1085, 1140 (1990)("efficient allocation of resources is more likely if product prices reflect their actual social costs, including the cost of product injuries that are economically or technologically unavoidable.").

Regulation, on the other hand, trumps private decisionmaking. As one scholar summarized:

> [U]nder a general deterrence regime, manufacturers, not government officials, make decisions about product safety. . . . In contrast, specific deterrence mandates a particular choice determined by the legislature or an administrative agency. *It is a raw exercise of state power* . . .

Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 Syracuse L. Rev. 897, 927 (1988)(emphasis added).

In view of this fundamental distinction, amicus suggests that tort liability inherently poses far less of a danger of conflict with federal regulatory efforts than state administrative requirements. It is improbable that Congress would view express preemption of state "requirements" as necessarily including both tort liability and state administrative regulation.

B. This Court Has Consistently Held That Preemption Of State Regulation Does Not Necessarily Include The Indirect Effects Of Tort Liability.

This Court's preemption decisions have long recognized the distinction between the indirect effect of tort liability on

private decisionmakers and direct government regulation. In *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 258 (1984), the Court found no inconsistency between "vest[ing] the NRC with exclusive regulatory authority over the safety aspects of nuclear development while at the same time allowing plaintiffs like Mr. Silkwood to recover for injuries caused by nuclear hazards." Indeed, both dissenting opinions agreed with the majority that, with respect to compensatory damages, preemption of state administrative regulation does not necessarily entail preemption of state tort remedies:

> Whatever compensation standard a State imposes, whether it be negligence or strict liability, a licensee remains free to continue operating under federal standards and to pay for the injury that results. . . . Compensatory damages therefore *complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme*.

Id. at 264 (Blackmun, J., dissenting)(emphasis added). Justice Powell's view was that, [t]here is no element of regulation when compensatory damages are awarded, especially when liability is imposed without fault, as authorized by state law. *Id.* at 276 n.3.

Relying on *Silkwood*, the Court later explained that:

> The effects of *direct* regulation on the operation of federal projects are significantly more intrusive than the *incidental* regulatory effects of such an additional award provision. Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers' compensation award if an employee's injury is caused by a safety violation. We believe Congress may reasonably determine that *incidental regulatory pressure is acceptable, whereas direct regulatory authority is not*.

Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 185 (1988)(emphasis added). Shortly thereafter, the Court reaffirmed the importance of this distinction:

> [F]or a state law to fall within the pre-empted zone, it must have some direct and substantial effect on the decisions made by those who build or operate nuclear facilities concerning radiological safety levels. We recognize that a claim for intentional infliction of emotional distress at issue here may have some effect on these decisions, because liability for claims like petitioner's will attach additional consequences to retaliatory conduct by employers. As employers find retaliation more costly, they will be forced to deal with complaints by whistleblowers by other means, including altering radiological safety policies. Nevertheless, we believe that this effect is neither direct nor substantial enough to place petitioner's claim in the preempted field.
>
> This result is strongly suggested by the decision in *Silkwood v. Kerr-McGee Corp.*

English v. General Electric Co., 110 S. Ct. 2270, 2278 (1990).

As Justice Blackmun later described the import of these decisions, "The level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory impact of the common law from positive enactments such as statutes and administrative regulations." *Cipollone, supra*, at 112 S. Ct. at 2628, 505 U.S. 536-37 (Blackmun, J., concurring in part, dissenting in part).

This distinction underlies the Court's approach to preemption under ERISA. In *Pilot Life Ins. Co. v. Dedeaux*, 107 S. Ct. 1549, 1554 (1987), the Court concluded that tort law is not a state law which "regulates" insurance, stating that a "common-sense view of the word 'regulates' would lead to the conclusion that in order to regulate insurance, a law must

not just have an impact on the insurance industry, but be specifically directed toward that industry".

The Court employed a similar analysis in *New York v. United States*, 112 S. Ct. 2408 (1992), finding that financial incentives to encourage states to enforce federal radioactive waste policy did not intrude upon state sovereignty protected by the Tenth Amendment. But "directly compelling them to enact and enforce a federal regulatory program" did. *Id.* at 2420.

II. COURTS MAY NOT FIND PREEMPTION OF STATE TORT REMEDIES UNLESS CONGRESS HAS CLEARLY AND UNAMBIGUOUSLY SO INTENDED.

A. Preemption of State Judicial Remedies Must Be Established by Clear and Unambiguous Statement of Congressional Intent to Protect State Sovereignty Guaranteed by the Tenth Amendment.

1. Regard for federalism requires a strong presumption against preemption of state tort law in the absence of clear and unambiguous Congressional intent.

Although the lower court recited the well-settled principle that there is a strong presumption against preemption of state tort remedies, Amicus submits that the evidence of congressional intent to eliminate product liability actions falls far short of what is necessary to overcome this presumption.

Recognizing that "the regulation of health and safety matters is primarily and historically a matter of local concern," *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707, 719 (1985), the Court has instructed that there is a strong "basic assumption that congress did not intend to displace state tort law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *Milwaukee v. Illinois*, 451 U.S. 304, 316 (1981). This Court has consistently adhered to the principle:

> [When Congress legislates] in a field which the States have traditionally occupied . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). This principle applies to the interpretation of express preemption provisions. *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2617 (1992), quoting *Rice*.

This presumption is not merely a rule of construction; it is an obligation of the judicial branch essential to avoid "unintended encroachments on the authority of the States." *CSX Transp. Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993).

Thus, "the ordinary rule of statutory construction [is] that if Congress intends to alter the 'usual constitutional balance between the States and the Federal Government,' it must make its intention to do so 'unmistakably clear in the language of the statute.'" *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 62 (1989), quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985).

2. Preemption of state tort remedies is an intrusion upon fundamental rights historically safeguarded by the states.

The strong presumption against preemption of state law is even stronger where preemption would leave injured persons without legal redress. Affording remedy for inury is a principal responsibility of government

> To take from an injured person all such remedies, without any replacement, threatens the very foundation of our legal system: "[T]he refusal to redress an otherwise actionable wrong creates disrespect for the law and encourages the victim to take matters into his own hands."

Carlisle v. Philip Morris, Inc., 805 S.W.2d 498, 512 (Tex. App. 1991), quoting *Lynn v. United Plant Guard Workers*, 383 U.S. 53, 64 (1966). The right to a remedy is expressly guaranteed by thirty-seven state constitutions. Francis E. McGovern, *The Variety, Policy and Constitutionality of Product Liability Statutes of Repose*, 30 Am. U.L. Rev. 579, 615 n.218 (1981); Note, *Constitutional Guarantees of a Certain Remedy*, 49 Iowa L. Rev. 1202 (1964).

The continued vitality of state constitutional protections of tort remedies is reflected in the decisions of state supreme courts striking down state legislation which limits recoverable damages. *See, e.g., Moore v. Mobile Infirmary Assoc.*, 592 So. 2d 156 (Ala 1991); *Smith v. Department of Insurance*, 507 So. 2d 1080 (Fla. 1987); *Kansas Malpractice Victims Coalition v. Bell*, 757 P.2d 251 (Kan. 1988); *Lucas v. United States*, 757 S.W.2d 686 (Tex. 1988); *Sofie v. Fibreboard Corp.*, 771 P.2d 711 (Wash. 1989).

3. Requiring Congress to speak plainly when preempting state law protects state sovereignty.

The Court gave substantive content to the Tenth Amendment[1] in *National League of Cities v. Usery*, 426 U.S. 833 (1976), holding Congress may not exercise power in a fashion that impairs the States' "traditional government functions" *Id.* at 854-55.

When the Court overruled *National League of Cities* a decade later in *Garcia v. San Antonio Metropolitan Transit Authority*. 469 U.S. 528 (1985), the Court did not devalue federalism, but concluded that it is "more properly protected by the procedural safeguards inherent in the structure of the federal system," through the states' representation in Congress. *Id.* at 552. This safeguard can be effective only

[1]The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.
U.S. Const., amend. X.

when courts require clear and unambiguous evidence that Congress indeed intended preemption. As Justice O'Connor has explained:

> By declining to infer preemption in the face of congressional ambiguity, the Court is . . . requiring that decisions restricting state sovereignty be made in a deliberate manner by Congress . . .
>
> Application of the plain statement rule thus may avoid a potential constitutional problem. Indeed, inasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise.

Gregory v. Ashcroft, 111 S. Ct. 2395, 2403 (1991).[2]

The strong presumption against preemption thus safeguards state autonomy. Laurence H. Tribe, American Constitutional Law § 6-25, at 479-80 (2d ed. 1988), quoted in *Gregory supra;* Barbara A. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 Buff. L. Rev. 181, 182 (1991); Paul Wolfson, *Preemption and Federalism: The Missing Link*, 16 Hastings Const. L.Q. 69, 112 (1988)("The

[2]State courts exhibit greater sensitivity than their federal counterparts to the incursions on state autonomy resulting from broad judicial declarations of preemption not supported by clearly and unambiguously articulated congressional intent:

> . . . if the common law claims of two hundred years are to be curtailed, if the courts of the States are to be deprived of deciding the cases that have been their historial province, if the supremacy clause is to mean preemption *uber alles*, then let the execution of the tort system be public. Let the sword of supremacy be wielded by congress in the full light of day . . .

Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 215 (Ill. App. 1994).

courts can, however, simultaneously protect the political safeguards of federalism and afford the necessary deference to Congress by requiring that Congress speak clearly and explicitly whenever it preempts state legislation.")

Judge Kenneth Starr has observed that the Court's increasing insistence upon a clear statement of congressional intent as a basis for preemption fosters a healthy federalism and accountability on the part of Congress. Kenneth Starr, et al., The Law of Preemption: A Report of the Appellate Judges Conference of the American Bar Association 40 & 50-55 (1991). It also preserves the proper role of the judicial branch, since "[w]hen judges preempt state laws in the absence of explicit congressional guidance, they in effect assume a legislative role without accepting legislative responsibility." *Id.* at 48.

B. Abolition of Common Law Remedies Without Alternative Means For Redress Is Constitutionally Suspect.

The presumption against preemption is even stronger where, as here, federal preemption of state law remedies provides no alternative means of redress. *See United Construction Workers v. Laburnum Const. Co.*, 347 U.S. 656, 663-64 (1954). As the Court explained in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984):

> This silence [of Congress] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.

464 U.S at 251. Justice Blackmun, dissenting in *Silkwood*, was equally emphatic on this point: "The absence of federal regulation governing the compensation of victims is strong evidence that Congress intended the matter to be left to the States." *Id.* at 264 n.7. *See also, Abbot v. American*

Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir. 1988)("The presumption is even stronger against preemption of state remedies, like tort recoveries, when no federal remedies exist.").

Amicus suggests that this is not merely a rule of construction. The common-law right to seek redress in the courts for wrongful injury holds a special place in our civil justice system. Indeed, they preceded even the Constitution. Lord Coke traced this right to the Magna Carta.[3] Chief Justice Marshall stated that

> the very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury. One of the first duties of government is to afford that protection.

Marbury v. Madison, 5 U.S. (1 Cranch) 137, 163 (1803). This right of access to justice is so fundamental that this Court has located "the duty of every State to provide, in the administration of justice, for the redress of private wrongs" in the Due Process Clause of the Fourteenth Amendment. *Missouri Pacific Ry. Co. v. Humes*, 115 U.S. 512, 521 (1885).

Indeed, the Court has suggested that the federal government's elimination of a state tort law remedy without providing some alternative recourse may violate substantive due process. In *Duke Power Co. v. Carolina Environmental Study Group*, 438 U.S. 59 (1978), the Court suggested that abolition of the common law right to a tort remedy in the Price-Anderson Act might violate due process but for the "panoply of remedies and guarantees" provided by Congress. *Id.* at 86-88 and 91-93. Justice Marshall later remarked that "our cases demonstrate that there are limits on governmental

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3 Every Subject may take his remedy by the course of the Law, and have justice, and right for the injury done to him, freely without sale, fully without denial, and speedily without delay.
Coke, Second Institute 55-56 (4th ed. 1671).

authority to abolish "core" common-law rights, . . . at least without a compelling showing of necessity or a provision for a reasonable alternative remedy." *PruneYard Shopping Center v. Robins*, 447 U.S. 74, 93-94 (1980)(Marshall, J., concurring).

Amicus submits that, while the lower court recited the formula of the presumption, 56 F.3d at 1341, the express preemption provision does not approach the clear and unambiguous expression necessary to overcome this presumption.

III. THE PLAIN TEXT OF THE MDA DOES NOT REFLECT A CLEAR AND MANIFEST INTENT TO PREEMPT STATE TORT LAW.

Cipollone's primary directive to federal courts is that the preemptive scope of a federal statute "is governed entirely by the express language." 112 S. Ct. at 2618. Section 360k(a) of the MDA provides:

> (a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement---
>
> (1) which is different from or in addition to, any requirement applicable under this Act to a device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

A. The Term "Requirement" Does Not Clearly And Unambiguously Include Product Liability.

In view of the sharp differences between regulation and liability actions, it is clear that the term "requirement" does not always, or even usually, refer to both. In *Cipollone*, this Court emphasized "there is no general, inherent conflict between federal preemption of state warning *requirements* and the continued vitality of state common law damages

actions." 112 S. Ct. at 2618 (emphasis added). Thus, even if a court may devise an interpretation of "requirement" that includes tort actions, it can, at best, suggest that the term is ambiguous. The lower court acknowledged that "Congress' choice of the word 'requirement' in §360k(a)(1), does not speak directly to the precise issue of whether Appellants' state common law tort claims are preempted by the MDA. As used in §360k(a), a 'requirement' refers to a legal obligation, . . . Even using this ordinary meaning, the scope of the word 'requirement' is ambiguous . . ." 56 F.3d at 1344.

Amicus suggests that in the face of such ambiguity, the strong presumption against preemption mandates that the court preserve the state law claims and reject preemption. As Justice Scalia observed, *Cipollone* requires that when a statute expressly preempts state law, "it must do so with great exactitude, as any ambiguity concerning its scope with be read in favor of preserving state power." 112 S. Ct. at 2634 (Scalia, J., dissenting). *See also Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2245 (1994)("But even accepting that §151a is susceptible of more than one interpretation, no proposed interpretation demonstrates a clear and manifest congressional purpose" to preempt state law).

B. The Plain Meaning Of The MDA Reflects Congressional Intent To Preempt State Administrative Regulation, Not Product Liability Actions.

1. The text of §360k(a) indicates that congress intended requirement to include only positive law.

The text of §360k(a) clearly indicates that Congress intended to preempt only legislative or administrative regulation. Congress uses the term "requirement" three times in this section. Two instances refer to a "requirement . . . under this Act," clearly a legislative or administrative requirement. Usage of the identical term, without further qualification or comment, to refer to preempted state law

suggests that Congress had in mind state legislative or administrative regulation."

2. A jury verdict does not establish a "requirement" with respect to a device.

It is important to ascertain precisely what is the offending state "requirement." The lower court indicated that it is the jury verdict in a products liability case that violates. §360k(a). 56 F.3d at 1343 ("it is for [the agency], not a jury . . ."). [4] Medtronic unequivocably asserts that it views the liability verdict as a "requirement." Medtronic Brief at 40 ("requirement . . . would be established by Florida state judges and juries"); and at 44 ("if plaintiffs' claims succeed" they would impose different or additional "requirements").

Indeed, nearly every court finding preemption under the MDA has viewed jury awards as establishing a state requirement. [5] *See Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744, 751 (M.D. Pa. 1992), *aff'd*, 5 F.3d 1489 (3d Cir. 1993)("A jury's finding of liability effectively creates a new standard or duty which defendants must follow."); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404, 407 (E.D. Mich. 1987)(A jury award "effectively compels the manufacturer to alter its warning to conform to different state law

[4]The lower court frequently refers to preemption of plaintiff's "claims" or "action." Since the Supremacy Clause provides for preemption only of state "law," this is not literally correct. It is reasonable to assume that the court refers to dismissal of claims because "if successful" the verdict would establish a requirement. *See King*, 983 F.2d at 1155, quoted in the text.

[5]*Cipollone* focused on generally applicable "legal duties" imposed by common law. 505 U.S. at 522. Section 360k(a), however, is narrower in scope, preempting only requirements "with respect to a device." General duties to exercise due care, to refrain from marketing unreasonably dangerous products, and to conform to warranties are not requirements "with respect to a device." They are requirements with respect to the conduct of product suppliers. Moreover, §360k(a) is limited to a requirement which "relates to the safety or effectiveness of *the* device." (emphasis added) General tort duties relate to all devices -- indeed, to all products.

requirements as 'promulgated' by the jury's findings.); *Covey v. Surgidev Corp.*, 815 F.Supp. 1089, 1094 (N.D. Ohio 1993)(great majority of courts have "reached the conclusion that a jury verdict in a tort suit under state law is a requirement" under the MDA). *See also King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993); *Stamps*, 984 F.2d at 1421; *Reeves v. Acromed Corp.*, 44 F.3d 300, 305 & 306 (5th Cir. 1995)(jury finding "tantamount to imposing a requirement").

This argument fundamentally misunderstands the role of the jury (or judge in a bench trial). The Supremacy Clause establishes preemption of state law. Jury's role, however, is to make findings of fact, not law. Medtronic's argument rests entirely on the notion that jury verdicts establish tort duties. The fact is that it is the breach of duty that gives rise to the jury verdict.

The fact is, a jury verdict in a product case "requires" only that the defendant pay compensation to the plaintiff. The court in *King v. Collagen Corp.* argued that: "If successful, the claim would require Collagen to redesign Zyderm, remove it from the market, or be subject to strict liability." 983 F.2d at 1135. However, this is precisely the range of options open at all times to any manufacturer whose product causes injury.

The jury's verdict imposes no legal obligation with respect to the product involved. Modifying the product does not preclude a subsequent plaintiff from establishing that it is unreasonably dangerous. [6] Nor does the manufacturer's decision not to make such a modification result in any legal consequence. A subsequent plaintiff must satisfy the same tort elements as the previous plaintiff. In short, the defendant retains the option of choosing between taking steps to prevent

[6]As a practical matter, it would be difficult to identify what action the jury's verdict might "require." Generally, a jury is asked to find whether the product is unreasonably dangerous; it does not determine what design or warning would be reasonably safe.

future harm or compensating future injured claimants. *See Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1540-41 (D.C. Cir. 1984); *Burke v. Dow Chemical Co.*, 797 F. Supp. 1128, 1138 (E.D.N.Y. 1992)(noting that *Ferebee* "remains a leading case"). In fact, a significant number of manufacturers who have been sued make the choice not to modify the product or warnings.[7]

It is true that the prospect of possible damage awards creates an incentive for the company to avoid future liability by improving the safety of its product. However, "[i]mposing a burden on the sale in the form of potential liability for defective design is distinguishable from a state seeking to exert actual control over the mode of manufacture or distribution of a specific product." *MacGillivray v, Lederle Laboratories*, 667 F. Supp. 743, 745 (D.N.M. 1987); Philip H. Corboy and Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption*, 15 Am. J. Trial Adv. 435, 452-57 (1992). *Compare, New York Conference of Blue Cross v. Travelers Ins.*, 115 S. Ct. 1671 (1995)(not every regulation that affects cost of insurance "relates" to benefit plans).

3. Product liability awards do not constitute a requirement established by the State.

A jury is not, a "State or political subdivision." Moreover, in ordinary parlance, a state does not "establish" or "continue" a jury verdict. Although a jury award is "only enforceable under state law" by entry of judgment by a court, it is not "imposed by the state." *Cipollone*, 112 S. Ct. at 2622 n.24.

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[7]E. Patrick McGuire, The Impact of Product Liability 18 (Conference Bd. 1988)("Nearly half of the companies with actual product liability experience . . . have improved their product use and warning materials. And a third say that they have redesigned their product lines to improve safety.")(context suggests substantial overlap of these two groups).

In this case, Medtronic's argument would lead to the ludicrous result that a federal jury sitting in a diversity case in federal district court would constitute a "State or political subdivision" within the meaning of the Act.

4. 360k(b) indicates that Congress intended to preempt only positive law.

Section § 360k(b), which authorizes the Secretary to exempt state requirements that are more stringent than FDA requirements or are compelled by local conditions, is clearly addressed to administrative regulation. One court has suggested application to damage awards would lead to "absurd" results. *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989). As two scholars have stated, §360k(b):

> is entirely inconsistent with an intent to have the term 'requirement' include the common law. . . . Clearly, Congress intended for this subsection to apply only to legislative type enactments by the states and not to common law tort claims.

Adler and Mann, *supra*, at 927-28 .

5. Section 360h(d) Reflects Congressional Intent To Preserve State Tort Actions

If Congress had intended to eliminate tort lawsuits, it would have employed language specifically denoting tort actions or common law actions. "Congress has long demonstrated an aptitude for expressly barring common law actions when it so desires." *Taylor v. General Motors Corp.*, 875 F.2d 816, 824 (11th Cir. 1989). *Pappas v. Upjohn Co.*, 926 F.2d 1019, 1023-24 (11th Cir. 1991)(same); *Worm v. American Cyanamid Co.*, 970 F.2d 1301, 1305 (4th Cir. 1993)("Congress has not failed to make such preemption clear when it desires to do so.").

Indeed, Congress employed very specific language in another section of the MDA when it intended to preserve

common law liability. 21 U.S.C. §360h provides that a "device . . . that presents an unreasonable risk of substantial harm to the public health" may be subject to an order by the Secretary requiring the repair, replacement, refund, or recall of the device. Congress then explicitly states:

> Compliance with an order issued under this section *shall not relieve any person from liability* under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 U.S.C. § 360h(d)(emphasis added).

This provision clearly reveals that Congress anticipated liability actions under state law would continue under the MDA. *See Mulligan v. Pfizer, Inc.*, 1994 WL 158819 (S.D. Ohio, April 1, 1994)(§360h(d) "specifically contemplates state law liability and damages"); *Truxillo v. Ray-Ban, Div. of Bausch & Lomb, Inc.*, 1992 WL 209302 (E.D. La., Aug. 11, 1992). If Congress had intended to include damage awards within the preemptive scope of §360k(a), it would have used equally clear and specific language. Adler and Mann, *supra*, at 929.

C. The Court's Decision in *Cipollone* Does Not Require that State Court Remedies Be Preempted Under the MDA.

1. Cipollone decision does not define "requirement" to include tort jury verdicts.

Medtronic relies heavily on what it construes as this Court's holding in *Cipollone* "applies directly to this case." Brief at 39.

Medtronic's attempt to import the Court's interpretation of "requirement" into a wholly unrelated statute flies in the face of *Cipollone's* central teaching, that the scope of express

preemption depends upon the text of the specific statute. 112 S. Ct. at 2618.

The text construed in *Cipollone* included the phrase "or prohibition." The Court found that some common law causes of action were preempted by the Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87, which provided in §5 "No *requirement or prohibition* based on smoking and health shall be imposed under State law." On the other hand, the 1965 Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §1334, which provided "No statement relating to smoking and health . . . shall be *required*" (emphasis added) preempted state legislative and administrative regulation, but not state law damage actions. *Id.* at 2619. In view of the plurality's statement that there is "no general, inherent conflict between federal preemption of state warning *requirements* and the continued vitality of state common law damages actions," 112 S. Ct. at 2618 (emphasis added), it seems clear that the Court viewed the words "or prohibition" as significant in expanding the preemptive scope to include tort actions. To the extent that *Cipollone's* definition of "requirement" is at all applicable to the MDA, it supports Amicus' argument that the term "requirement" does not itself necessarily encompass product liability actions.

2. Garmon does not support preemption.

Medtronic also relies on a statement in *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959), that state "regulation can be as effectively asserted through an award of damages as through some form of preventive relief." Brief at 37.

In that case, however, it was not necessary for the Court to distinguish between the incidental effects of tort law and direct regulation. Rather, the statutory scheme in that case deprived state courts of jurisdiction entirely.

In *Garmon*, an employer won damages in a tort action in California state court against a labor union that had picketed

plaintiff's lumber business. Reversing, the Supreme Court ruled that with respect to such activities, "the States as well as the federal courts must defer to the exclusive competence of the National Labor Relations Board." *Id.* at 245. As this Court later explained, *Garmon* was chiefly concerned with "ensuring that the primary responsibility for interpreting and applying this body of law remained with the NLRB. . . based on the primary jurisdiction rationale." *Brown v. Hotel & Restaurant Employees & Bartenders International Union Local 54*, 468 U.S. 491, 502 (1984). *See also English v. General Electric Co.*, 496 U.S. 72, 86-87 n.8 (1990).

It is also significant that the *Garmon* Court carefully conditioned its ouster of state law on the understanding that access to justice would be assured through alternative federal remedies. The majority opinion emphasized the fact that NLRA established a set of procedures and remedies in place of the state law remedies displaced by the Act. 359 U.S. at 243. The concurring justices cautioned that, where Congress has not provided a remedy for tortious conduct, "there is no ground for concluding that existing criminal penalties or liabilities for tortious conduct have been eliminated." *Id.* at 252 (Harlan, J., concurring), quoting *United Construction Workers v. Laburnum Const. Co.*, 347 U.S. 656, 665 (1954).

IV. THE LEGISLATIVE BACKGROUND OF MDA DOES NOT INDICATE CONGRESSIONAL INTENT TO PREEMPT PRODUCT LIABILITY ACTIONS.

In *Cipollone*, the Court held that the 1965 Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §1334, did not preempt state law damage actions. 112 S. Ct. at 2619. The Court based its interpretation on the express language of the statute "[r]ead against the backdrop of regulatory activity undertaken by state legislatures and federal agencies" which "were the catalyst for passage of the 1965 Act." *Id.* It is therefore appropriate to examine the MDA's "legislative context."*Id* at n.16.

A. Congress Intended To Make Regulation Of Devices More Consistent With Regulation Of Drugs Under The Parent Statute, Which Does Not Preempt Tort Law.

Congress did not enact the MDA in a vacuum. The amendments were intended to remedy deficiencies in the Federal Food Drug and Cosmetic Act of 1938, 21 U.S.C. §§321-92 It is well-settled that regulations under the FDCA do not preempt state tort causes of action. *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1176-77 (5th Cir. 1988); *Abbott v. American Cyanamid Co.*, 844 F.2d 1108, 1112 & n.1 (4th Cir.), cert. denied, 488 US 908 (1988). Indeed Congress explicitly rejected a proposed "right of action for damages" for violation of the Act as unnecessary because plaintiffs would continue to have a common law cause of action. Hearings on S. 1944 Before a Subcommittee of the Committee on Commerce, U.S. Senate, 73rd Cong., 2d Sess. 400 (1933). *See Consumer Federation of America v. Upjohn*, 346 A.2d 725, 731 (D.C. App. 1975)(citing legislative history). Congress could reasonably have understood that product liability actions would continue under the 1976 amendments to that statute.

Additionally, one goal of the MDA was the elimination of definitional disputes between FDA and manufacturers as to whether a product would be classified as a drug or as a far less regulated device. Gail H. Javitt, *supra*, at 566-68. It would be anomalous for Congress to perpetuate this problem by bestowing immunity from tort liability only upon device manufacturers.

B. If Congress Intended To Eliminate Products Liability, It Would Have Done So Explicitly.

The catalyst that resulted in passage of the MDA was the Dalkon Shield scandal. "This contraceptive device, as well as heart valves and pacemakers, became the symbols that spurred Congressional action to protect the public from the harmful effects of a largely unregulated device industry."

Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1434 (C.D. Cal. 1994). *See also Michael v. Shiley, Inc.*, 46 F.3d 1316, 1319 (3rd Cir. 1995); *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 753 (S.D.N.Y. 1994). Witness after witness in congressional hearings decried the numerous injuries and deaths caused by this device. *See* S. Rep. No. 94-33, 94th Cong., 2d Sess. (1976), reprinted in 1976 U.S. Code & Admin. News 1070, 1071. Laura K. Jortberg, *Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments Under* Slater v. Optical Radiation Corp., 43 DePaul L. Rev. 963, 978 (1994).

Those injuries and deaths occasioned numerous lawsuits against the manufacturer, A.H. Robins Co., including a verdict for puntive damages. *Deemer v. A.H. Robins Co.*, No. C-30649 (Kan. Dist. Ct., Feb. 7, 1975). By 1976, Dalkon Shield lawsuits were the largest category of product liability actions pending in federal court, outnumbering by far even asbestos cases. U.S. General Accounting Office, Product Liability: Extent of "Litigation Explosion" in Federal Courts Questioned, HRD-88-36BR (Jan. 1988) at 22.

Congress was well aware of these lawsuits. "Presently, more than 500 lawsuits seeking compensatory and punitive damages totaling more than $400 million are pending against the manufacturer of the Shield.." H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976). Under those circumstances, ATLA suggests, it is inconceivable that Congress would have acted to eliminate such civil actions without significant debate. However, "careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Adler and Mann, *supra*, at 922 n.128.

C. Congress Intended § 360k(a) To Apply to State Administrative Regulation.

The lower court imputed to Congress "twin purposes" in enacting the MDA: Protection of the public, counterbalanced by avoidance of overregulation that might stifle progress.

Lohr, 56 F.3d at 1335. development. However, the exerpt from the House Report quoted by the court explicitly cautions against "excessive or ill-conceived *Federal* device regulation." *Id.*, quoting H.R. Rep. No. 853, 94th Cong., 2d Sess. 10 (1976). Congress made no reference to state product liability lawsuits. *See* Adler and Mann, *supra*.

The only discussion in the legislative history concerning the motivation behind §360k concerns state administrative regulation:

> In absence of effective Federal regulation of medical devices some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. . . . Implementation of the Sherman Law has resulted in the *requirement* that intrauterine devices are subject to premarket clearance in California.

House Rep. No. 853, 94th Cong., 2d Sess. at 45-46 (1976)(emphasis added).

This is precisely the type of "backdrop of regulatory activity undertaken by state legislatures" which convinced the *Cipollone* court that "no statement relating to smoking and health shall be required" included only positive law, not common law liability. 112 S. Ct. at 2619. *See also Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 754-55 (S.D.N.Y. 1994); *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667-68 (D. Md. 1989).

V. THE FDA DOES NOT INTERPRET THE MDA AS PREEMPTING PRODUCT LIABILITY ACTIONS.

The lower court properly relied on the FDA's interpretation of "requirement" under the MDA. 56 F.3d at 1344-45. However, the court failed to accord any weight to

the FDA's view that state "requirement" does not include product liability actions.

This Court has instructed that "the construction of a statute by those charged with its administration is entitled to substantial deference." *United States v. Rutherford*, 442 U.S. 544, 553 (1979). Indeed, the Court has deemed the FDA's interpretation of its own regulations "dispositive" on the issue of preemption of state law. *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S 707, 714 (1985).

21 C.F.R. 808.1(d)(1) provides:

> Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

Actions based on implied warranty of fitness without privity are substantially identical to strict liability actions. *See* Restatement (Second) of Torts § 402A (1965) comment *m*. Strict liability, as well as negligence, fraud, and misrepresentation, relate to all products in addition to devices. apply to product suppliers generally and are not limited to devices. The FDA clearly does not view product liability as preempted by §360k(a).

Several courts have discerned a contrary view in 21 C.F.R. §808.1(b), which declares that no state "may establish or continue in effect any requirement with the force and effect of law (whether established by statute, ordinance, regulation, *or court decision*)(emphasis added). See *Stamps*, 984 F.2d at 1421 nn. 1 & 2. However, the FDA did not intend the term "court decision" to refer to common law causes of action for damages. Jury verdicts are not court decisions. Moreover, the

regulation subsequently makes it clear that it refers to court decisions interpreting positive law enactments:

> In determining whether such a [state] requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the state or local government and not the literal language of the *state statute* which may be identical to a provision in the act.

21 C.F.R. 808.1(d)(6)(ii)(emphasis added). As the FDA explained the regulation in connection with its promulgation as a final rule:

> When determining whether a State or local requirement is preempted, however, the Commissioner will consider how the requirement is interpreted and applied, not merely the literal language of the *applicable statute*.

43 Fed. Reg. 18663 (May 2, 1978)(emphasis supplied).

The agency has consistently adhered to its view that the MDA does not preempt product liability. 21 C.F.R. §808.5 authorizes the Commissioner to issue advisory opinions "concerning preemption of State or local device requirements." The advisory opinion "[r]epresents the formal position of the FDA" and is binding on the agency. 21 C.F.R. §10.85(e). In one such opinion, the Office of the Chief Counsel for the FDA stated:

> *There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies*, . . . Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

Advisory Opinion by Joseph P. Hile, Associate FDA Commissioner for Regulatory Affairs, Docket No. B3A-0140/AP, Mar. 2, 1984. *quoted in Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1435 (C.D. Cal. 1994); reprinted in Pet. App. 4a-6a.

The Chief of the Regulations Staff subsequently restated that this interpretation that "the FDA believes that Section 521 does not preempt general product liability requirements." Letter from Joseph Sheehan, Chief, Regulations Staff, Food and Drug Administration, to Cindy Whaley, Esq. (Feb. 2, 1987) reprinted at Pet. App. 7a

CONCLUSION

For these reasons, Amicus urges the Court to reverse the order of the lower court in this case.

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OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/
Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/
Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF AMICI CURIAE FOR THE CENTER FOR PATIENT ADVOCACY AND THE CALIFORNIA HEALTH CARE INSTITUTE IN SUPPORT OF PETITIONER/CROSS-RESPONDENT

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
STATEMENT OF INTEREST OF AMICI CURIAE	1
SUMMARY OF ARGUMENT	4
ARGUMENT	5
I. THE MDA ESTABLISHED A COMPREHENSIVE REGULATORY SCHEME DESIGNED TO ENSURE THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES AND TO PROMOTE INNOVATION IN MEDICAL DEVICE TECHNOLOGY	5
II. SUBJECTING MEDICAL DEVICE MANUFACTURERS TO LIABILITY UNDER THE PATCHWORK OF STATE TORT LAW REGIMES WOULD STIFLE INNOVATION IN MEDICAL DEVICE TECHNOLOGY AND DRIVE EXISTING, FDA-CLEARED PRODUCTS FROM THE MARKETPLACE TO THE DETRIMENT OF PATIENT CARE	11
III. TO GIVE FULL EFFECT TO THE REGULATORY SCHEME ESTABLISHED BY THE MDA, THIS COURT SHOULD HOLD THAT STATE COMMON LAW CLAIMS BROUGHT AGAINST MANUFACTURERS OF FDA-CLEARED MEDICAL DEVICES ARE PREEMPTED	23
CONCLUSION	28

TABLE OF AUTHORITIES

Cases — Page

Brown v. *Superior Court*, 751 P.2d 470 (Cal. 1988) 18
Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) 24
Daubert v. *Merrell Dow Pharmaceuticals*, 43 F.3d 1311 (9th Cir.), *cert. denied*, 116 S. Ct. 189 (1995) 20
Duvall v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir.), *petition for cert. filed*, No. 95-1010 (Dec. 22, 1995) 25
English v. *General Electric Co.*, 496 U.S. 72 (1990) 23, 26
International Paper Co. v. *Ouellette*, 479 U.S. 481 (1987) 24
Leatherman v. *Tarrant County Narcotics Intelligence & Coordination Unit*, 113 S. Ct. 1160 (1993) 26
New York State Conference of Blue Cross & Blue Shield Plans v. *Travelers Insurance Co.*, 115 S. Ct. 1671 (1995) 23
Pacific Mutual Life Insurance Co. v. *Haslip*, 499 U.S. 1 (1991) 14
Slater v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992) 25
TXO Production Corp. v. *Alliance Resources Corp.*, 113 S. Ct. 2711 (1993) 14

Statutory Provisions

21 U.S.C. § 360(k) 10
21 U.S.C. § 360c 8
21 U.S.C. § 360c(a) (1) 8
21 U.S.C. § 360c(a) (1) (A) 9
21 U.S.C. § 360c(a) (1) (A) (i) 6
21 U.S.C. § 360c(a) (1) (B) 6, 9
21 U.S.C. § 360c(a) (1) (C) (ii) (I) 9
21 U.S.C. § 360c(a) (1) (C) (ii) (II) 9
21 U.S.C. § 360c(f) (1) (A) (ii) 9
21 U.S.C. § 360c(i) (1) (A) 9, 10
21 U.S.C. § 360e(a) 9

TABLE OF AUTHORITIES—Continued

Page

21 U.S.C. § 360e(b) 10
21 U.S.C. § 360e(b) (1) (A) 9
21 U.S.C. § 360e(b) (1) (B) 9
21 U.S.C. § 360e(c) (1) 9
21 U.S.C. § 360e(d) (2) 6
21 U.S.C. § 360h(e) (1) (A) 10
21 U.S.C. § 360h(e) (1) (B) 10
21 U.S.C. § 360i 10
21 U.S.C. § 360j(g) 11
21 U.S.C. § 360j(g) (1) 6
21 U.S.C. § 360j(g) (2) (A) 9
21 U.S.C. § 360j(k) 6, 11
21 U.S.C. § 360j(m) 11
21 U.S.C. § 360k(a) 11, 24
21 U.S.C. § 360k(a) (1) 3, 4, 11, 23
21 U.S.C. § 360k(b) 11, 26
21 U.S.C. § 360*l* 10

Regulatory Provisions

21 C.F.R. Part 801 10
21 C.F.R. Part 820 10
21 C.F.R. § 803.1 10
21 C.F.R. § 803.24 10
21 C.F.R. § 807.87 ..... 9, 10
21 C.F.R. § 807.87(k) 10
21 C.F.R. § 807.92 10
21 C.F.R. § 807.100 9
21 C.F.R. § 807.100(a) (3) 10
21 C.F.R. § 807.100(b) 10
21 C.F.R. § 872.6855 9
21 C.F.R. § 890.3860 9
Final Policy Statement of Dep't of Health & Human Services/Food & Drug Admin., 56 Fed. Reg. 46,191 (Sept. 10, 1991) 10

Legislative Materials

Entrepreneurship in America: Loosening the Government Noose on Small Business, Field Hearing Before the Senate Comm. on Small Business, 104th Cong., 1st Sess. (1995) 13

TABLE OF AUTHORITIES—Continued

	Page
Health Care Liability Reform and Quality Assurance Act of 1995, Hearing on S. 454 Before the Senate Comm. on Labor and Human Resources, 104th Cong., 1st Sess. (1995)	13
Medical Devices: Hearing Before the Senate Comm. on Labor and Human Resources, 101st Cong., 2d Sess. (1990)	8
Medical Device Safety: Hearings on H.R. 3095 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 101st Cong., 2d Sess. (1990)	8, 12
Product Liability Fairness Act: Hearings on S. 640 Before the Subcomm. on Consumer of the Senate Comm. on Commerce, Science, and Transportation, 102d Cong., 1st Sess. (1991)	13
Product Liability: Hearing Before the Subcomm. on Technology and Competitiveness of the House Comm. on Science, Space, and Technology, 102d Cong., 2d Sess. (1992)	13, 18
Reforming the FDA: Hearing Before the Subcomm. on Health and Environment of the House Comm. on Commerce, 104th Cong., 2d Sess., 1996 WL 5508897, 5508917 (Feb. 27, 1996)	12-13, 19, 21
H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976)	7, 24
S. Rep. No. 33, 94th Cong., 2d Sess. (1976)	7, 12
S. Rep. No. 513, 101st Cong., 2d Sess. (1990)	7
121 Cong. Rec. S1258 (daily ed. Jan. 30, 1975)	7-8
122 Cong. Rec. H1722 (daily ed. Mar. 9, 1976)	8
122 Cong. Rec. H1725 (daily ed. Mar. 9, 1976)	8
136 Cong. Rec. S12493 (daily ed. Aug. 4, 1990)	8
136 Cong. Rec. S15210 (daily ed. Oct. 12, 1990)	8
136 Cong. Rec. S17457 (daily ed. Oct. 27, 1990)	8
U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, OTA-H-522 (Feb. 1993)	18

TABLE OF AUTHORITIES—Continued

Other

	Page
American Medical Association, *Report of Board of Trustees: Impact of Products Liability on the Development of New Medical Technologies* (June 1988)	17
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Malcolm Gladwell, *U.S. Firms Abandoning Birth Control Industry in Wake of Lawsuits*, Wash. Post, May 1, 1988	19
Trisha Gura, *Implant Debate to Cripple Innovation?: Liability Fears May Impede Testing, Limit Supplies*, Chi. Trib., Mar. 13, 1995	16, 22
Martin J. Hatlie *et al.*, *Health Care Liability: Reform in a Changing Environment*, in *State and Civil Justice Reform* (Roger Clegg ed. 1994)	18
Charles H. Hennekens *et al.*, *Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals: A Retrospective Cohort Study*, 275 J. Am. Med. Ass'n 616 (1996)	16
David S. Hilzenrath *et al.*, *Surviving the Breast Implant Siege*, Wash. Post, June 24, 1994	16

TABLE OF AUTHORITIES—Continued

	Page
Peter W. Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 Colum. L. Rev. 277 (1985)	18
Richard J. Mahoney, *Product Liability and Punitive Damages Laws Stifle Creativity and Innovation, Introduction* to Jacqueline R. Denning *et al., Pernicious Ideas and Costly Consequences: The Intellectual Roots of the Tort Crisis* (Nat'l Legal Center for the Pub. Interest 1990)	17-18
Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years*, 50 Food & Drug L.J. 163 (1995)	6
Richard Neely, *The Product Liability Mess: How Business Can Be Rescued From the Politics of State Court* (1988)	14, 15
Jorge Sanchez-Guerrero *et al., Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 New Eng. J. Med. 1666 (1995)	16
Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1 (1993)	14, 21
The Liability Maze: The Impact of Liability Law on Safety and Innovation (Peter W. Huber and Robert E. Litan eds. 1991)	14, 18, 21
Trends in Venture Capital Funding for the Medical Device Industry (Health Care Technology Inst. Mar. 1994)	13
Truth, Justice & Implants, Wall St. J., Feb. 26, 1996	16
W. Kip Viscusi, *Reforming Products Liability* (1991)	19

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

Nos. 95-754 & 95-886

MEDTRONIC, INC.,
Petitioner/
Cross-Respondent,
v.

LORA LOHR and MICHAEL LOHR,
Respondents/
Cross-Petitioners.

On Writs of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

BRIEF AMICI CURIAE FOR THE CENTER FOR PATIENT ADVOCACY AND THE CALIFORNIA HEALTH CARE INSTITUTE IN SUPPORT OF PETITIONER/CROSS-RESPONDENT

STATEMENT OF INTEREST OF AMICI CURIAE

Amici are the Center for Patient Advocacy (CPA) and the California Health Care Institute (CHI).[1] CPA

[1] This brief is filed with the consent of the parties. Copies of the consent letters have been filed with the Clerk.

is a private, non-profit organization founded in 1995 to represent the interests of patients nationwide in obtaining access to safe, state-of-the-art medical care. Its members include citizens concerned about the quality of patient health care in America today; physicians and other health-care providers interested in providing their patients with the safest, most effective medical care available; and pharmaceutical and bioengineering firms engaged in the development of new medical products and concerned about the inhibiting effect of excessive government regulation and state products liability laws on their efforts to provide patients with the latest medical technology.

CPA develops and supports initiatives aimed at eliminating and reducing the restrictions imposed by both government and the private sector on the development of and access to new medical products, including both drugs and devices. CPA has proposed a number of legislative and regulatory reforms aimed at ensuring that Americans have access to safe, innovative medical treatments as soon as feasible. CPA also supports tort law reform efforts aimed at reducing the inhibiting effect that excessive liability has on patients' timely access to new medical technologies and on physicians' ability to provide the latest medical innovations to their patients. CPA's officers have testified before Congress on numerous occasions on these and related matters.

CHI is a private, non-profit organization founded in 1993 to represent the interests of California's biomedical and health care technology industry. Its members include academic research institutions as well as numerous biotechnology, medical device, and pharmaceutical firms. CHI's efforts are aimed at establishing a favorable climate for scientific discovery and innovation in the emerging medical products field. CHI conducts economic and public policy research, produces industry analyses, provides educational programs, formulates policy, and advocates the implementation of that policy at both the federal and state levels. Among other things, CHI has initiated and supported efforts to reform state products

liability laws and to provide specific protections for the suppliers of the biomaterials on which literally thousands of life-saving medical devices depend.

This case concerns whether federal law preempts state common law actions that seek to hold medical device manufacturers liable for the manufacture, labeling, or design of devices cleared for marketing to the public by the United States Food and Drug Administration (FDA) under the comprehensive regulatory scheme established by the Medical Device Amendments of 1976 (MDA or the Act), 21 U.S.C. §§ 360c-360*l*. The Court's decision will have serious implications for the quality of patient care today and for the development of new, improved, and safer medical device technology in the future.

Amici's participation will provide the Court with a broader perspective on the practical consequences of subjecting medical device manufacturers to liability under the patchwork of state tort law regimes in this country for the manufacture, labeling, or design of devices reviewed by the FDA and cleared for marketing to the public at large. Amici believe that exposing manufacturers to often excessive and unpredictable liability under divergent state tort law systems will not only stifle innovation in the emerging medical device field, but actually will diminish the quality of patient care as manufacturers withdraw existing, FDA-cleared products from the marketplace.

Congress intended to prevent this very result by enacting the MDA and, in particular, by expressly prohibiting the imposition of any state law requirements with respect to medical devices that are "different from, or in addition to" the requirements established under the MDA. 21 U.S.C. § 360k(a)(1). Amici have a direct interest in ensuring that this Court gives full effect to that unambiguously expressed intent of Congress.

SUMMARY OF ARGUMENT

The divergent patchwork of state products liability laws in this country imposes a "liability tax" that is passed on to all of us in the form of increased product costs and insurance premiums. In the case of medical products, however, products liability laws exact an additional, far greater societal toll: they stunt the development of new and improved medical products and drive existing products from the marketplace. Thus, many potentially life-saving medical products are not developed by manufacturers today because of liability concerns, and existing, FDA-cleared products are pulled from the market by manufacturers facing massive liability in suits brought by users, even though in many cases there is no scientifically credible evidence that these products are harmful. The quality of patient care in this country suffers as a result.

Congress was well aware of the compelling need to promote innovation in medical device technology when it enacted the MDA, and sought to do so by promoting research and development of investigational devices and by minimizing government interference in other development efforts. More to the point, Congress expressly preempted any state requirements that are "different from, or in addition to" the requirements for medical devices established under the MDA. 21 U.S.C. § 360k(a)(1). In enacting the MDA, Congress also sought to ensure the safety and effectiveness of products entering the marketplace. Thus, Congress established a comprehensive regulatory scheme under which devices must undergo FDA scrutiny as to safety and effectiveness, manufacturers must obtain FDA clearance before marketing their devices, and manufacturers remain under continuing FDA oversight and reporting requirements if and when their products reach the market. Congress also understood, however, that by promoting innovation in medical device technology—including by relieving manufacturers of regulation under state law—it would be contributing to the development of generation after generation of safer, more effective products to the benefit of patient care.

This case presents the question whether the MDA preempts state common law claims against manufacturers of FDA-cleared devices for manufacturing, labeling, or design defects. Congressional intent is the touchstone of this Court's preemption analysis. Here, honoring that intent requires holding these state law claims preempted. There is no basis for concluding, as did the court below, that some state products liability claims—but not others—should be preempted. That would contravene Congress' intent, because it would trigger the same liability concerns and thus undermine—if not entirely defeat—Congress' efforts to foster innovation in the emerging medical device industry and thereby improve the quality of patient care. Holding state common law claims preempted will not threaten the safety or effectiveness of medical devices marketed for public use. In enacting the MDA, Congress decided to rely on comprehensive federal regulation and FDA oversight—not lay juries charged with applying state products liability laws—to ensure medical device safety and effectiveness.

That was a wise decision. It is, in any event, not for this Court to second-guess that policy judgment here. Instead, this Court should give full effect to the unambiguously expressed intent of Congress. The quality of patient care and the prospects for the development of new, improved, and safer medical devices depend on it.

ARGUMENT

I. THE MDA ESTABLISHED A COMPREHENSIVE REGULATORY SCHEME DESIGNED TO ENSURE THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES AND TO PROMOTE INNOVATION IN MEDICAL DEVICE TECHNOLOGY.

1. Medical devices have been around for centuries. King George III was placed in restraints to "treat" his affliction with what is now believed to have been a metabolic disorder. George Washington is said to have had wooden teeth. Melville's Captain Ahab moved about

with the assistance of a prosthetic—albeit wooden—leg. Thomas Edison used a cornucopia horn to listen to his phonograph. President Franklin Roosevelt, like others in his generation who were afflicted by polio, walked only with the assistance of metal leg braces and other mechanical aids.

For most of our history, advancements in medical device technology have been unforthcoming, or sporadic at best. In the past few decades, however, medical device technology has flowered along with medical science as a whole. Devices that were unthinkable a short while ago—ultrasound imaging machines, implantable heart defibrillators, artificial joints made of synthetic materials, and intraocular lenses—have become everyday treatment options. These devices have enabled Americans to live longer, healthier, and more productive lives. New and even more breathtaking advances—including artificial organs—are currently being developed and other, perhaps unimaginable breakthroughs lie on the horizon.

2. In 1976, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) with the passage of the MDA, ushering in a new era of comprehensive federal regulation of medical devices.[2] Through this Act, Congress sought to accomplish two principal objectives: first, to protect the public by ensuring that medical devices would not be marketed until they were proven to be safe and effective, *see, e.g.*, 21 U.S.C. §§ 360c(a)(1)(A)(i), 360c(a)(1)(B), 360e(d)(2); and second, to foster innovation in medical device technology and thereby promote the development of new and improved devices. *See, e.g., id.* §§ 360j(k), 360j(g)(1). These purposes complement one another as advances in medical device technology result in safer, more effective products for use in treating patients.

[2] For a review of the history of federal regulation of medical devices prior to the MDA, see Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years*, 50 Food & Drug L.J. 163, 163-167 (1995).

References to these twin objectives abound throughout the legislative history of the MDA. For example, the Senate Report accompanying the MDA states:

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee [on Labor and Public Welfare] wants to encourage their research and development. [S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1976).]

The original House Report provides:

> Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in the field. [H.R. Rep. No. 853, 94th Cong., 2d Sess. 10 (1976).]

See also id. at 12 (the MDA "reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research"); *id.* at 42 ("recogniz[ing] the necessity to encourage the discovery and development of medical devices intended for human use").

Congress reaffirmed this intent when it amended the MDA in 1990:

> Simply put, the [MDA] sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and the government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices. [S. Rep. No. 513, 101st Cong., 2d Sess. 13 (1990).[3]]

[3] Floor statements made during the debates on the MDA and 1990 amendments are to the same effect. *See, e.g.*, 121 Cong. Rec.

3. In order to achieve these objectives, Congress established a comprehensive scheme for the regulation of all "devices intended for human use." 21 U.S.C. § 360c (a)(1). The MDA authorizes the FDA to classify medical devices into three separate categories based on the degree of regulation necessary to assure "safety and effectiveness." *Id.* § 360c. This case concerns a Class III device manufactured by petitioner/cross-respondent Medtronic, Inc. (Medtronic)—the cardiac pacemaker lead.[4] Class III devices are "for use in supporting or sustaining

S1258 (daily ed. Jan. 30, 1975) (Senate Health Subcommittee) ("recogniz[ing] the necessity to encourage scientific investigation in the medical devices field"); 122 Cong. Rec. H1722, H1725 (daily ed. Mar. 9, 1976) (statements of Rep. Carter) (recognizing "the need to continue to encourage scientific investigation and to assure product innovation"); 136 Cong. Rec. S12493 (daily ed. Aug. 4, 1990) (statement of Sen. Dodd) (the MDA "is structured to guard against excessive governmental restrictions which might inhibit innovation in the development and advancement of biomedical products"); *id.* at S15210 (daily ed. Oct. 12, 1990) (statement of Sen. Kennedy) (recognizing the need to ensure "that growth and innovation in the medical device field continue"); *id.* at S17457 (daily ed. Oct. 27, 1990) (statement of Sen. Dodd) (the MDA sought to "foster incentives to encourage innovation in a relatively youthful industry").

These concerns were expressed during hearings on these acts as well. *See, e.g., Medical Device Safety: Hearings on H.R. 3095 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 101st Cong., 2d Sess. 73-74 (1990) [hereinafter *Hearings on Medical Device Safety*] (statement of Rep. Towns) ("As we craft new legislation, we must be careful to preserve the incentives for innovation that have pushed the frontiers of health technology forward"); *Medical Devices: Hearing Before the Senate Comm. on Labor and Human Resources*, 101st Cong., 2d Sess. 3 (1990) (statement of Sen. Hatch) ("we should work to balance the need for regulation with the benefits of innovation"); *id.* at 52 (statement of Sen. Dodd) (recognizing the consumer interest in "getting the state-of-the-art, the most modern and effective medical devices on the market").

[4] The device manufactured by Medtronic is part of a pacemaker system implanted in the body to assist the heart's natural beat by transmitting small electronic pulses from the pacemaker to the heart and by returning signals from the heart to the pacemaker. *See* Pet. Br. at 2.

human life." *Id.* § 360c(a)(1)(C)(ii)(I). They "present[] a potential unreasonable risk of illness and injury." *Id.* § 360c(a)(1)(C)(ii)(II). As a result, they are subject to the most stringent federal regulation.[5]

The FDA's review of Class III devices is governed by a complex web of federal rules and regulations. Some Class III devices are required to undergo a premarket approval (PMA) process. As part of that process, manufacturers must submit detailed information to the FDA concerning, *inter alia*, intended use, design specifications, manufacturing methods, performance standards, and labeling. *Id.* § 360e(c)(1). Two categories of Class III devices were excluded from the Act's PMA requirement: devices introduced prior to May 28, 1976 (the effective date of the MDA), *id.* § 360e(b)(1)(A), and certain investigational, or "IDE" devices under clinical scrutiny for safety and effectiveness. *Id.* § 360j(g)(2)(A). While already-marketed devices are not statutorily required to undergo PMA review, the FDA may require any such device to obtain premarket approval when necessary to assure product safety or effectiveness. *See* Pet. Br. at 8-9.

If a proposed Class III device is "substantially equivalent" to an already-marketed device, including one grandfathered under the Act, it is subject to the "510(k) process." *See* 21 U.S.C. § 360e(b)(1)(B); 21 C.F.R. § 807.100. Under this process, manufacturers must demonstrate to the FDA that the device in fact meets the federal "substantial equivalen[ce]" test. 21 U.S.C. §§ 360c(f)(1)(A)(ii), 360e(a). That requires showing, *inter alia*, that the device is as "safe and effective as a legally marketed device." *Id.* § 360c(i)(1)(A); 21

[5] The first two classes under the MDA are reserved for devices that pose less risk to their users. Class I devices, such as the toothbrush, pose little or no safety threat and are subject only to certain generally applicable regulations. 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 872.6855. Class II devices, such as the powered wheelchair, pose a somewhat greater risk to their users, and therefore are subject to certain device-specific controls. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 890.3860.

C.F.R. §§ 807.87, 807.100(b).[6] As part of this showing, manufacturers are required to submit detailed information to the FDA. 21 U.S.C. § 360(k); 21 C.F.R. §§ 807.87, 807.92.[7] Upon receipt of this information, the FDA may either clear the product for marketing, block its entry, or require the submission of additional data. 21 C.F.R. § 807.100(a)(3). As in the case of any already-marketed device grandfathered under the Act, the FDA may require any device subject to the 510(k) process to undergo PMA review as well. 21 U.S.C. § 360e(b).[8]

Only devices that clear these hurdles may be marketed to the public. Every device marketed for public use must be manufactured and labeled in accordance with federal standards, *see* 21 C.F.R. Parts 801, 820, and remains under the continuing supervision and control of the FDA. After a device reaches the market, the FDA may require manufacturers to submit additional information. 21 C.F.R. § 807.87(k). In addition, manufacturers themselves remain subject to recordkeeping and reporting obligations, which, *inter alia*, require manufacturers immediately to report any serious device malfunction. 21 U.S.C. §§ 360i, 360*l*; 21 C.F.R. §§ 803.1, 803.24. At any point, the FDA may rescind its marketing approval, 56 Fed. Reg. 46,191, 46,194 (Sept. 10, 1991), bar the distribution of devices, 21 U.S.C. § 360h(e)(1)(A), or recall a device altogether. *Id.* § 360h(e)(1)(B). The FDA also may seek civil and criminal penalties against manufacturers that violate MDA requirements. *See* Pet. Br. at 7.

[6] Congress codified the FDA's long-standing interpretation of "substantial equivalence," which focused on comparing the safety and effectiveness of the proposed and previously marketed devices, under the 1990 amendments to the MDA. *See* Pet. Br. at 25-26.

[7] The required information relates to device design as well as device safety and effectiveness. *See* 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. §§ 807.87, 807.92, discussed in Pet. Br. at 22-23.

[8] The medical device involved in this case eventually reached the market via the 510(k) process, but not before the FDA had required Medtronic to submit additional data concerning device design. *See* Pet. Br. at 10-11.

4. The foregoing provisions are aimed primarily at ensuring the safety and effectiveness of medical devices that enter the marketplace. As discussed, this was only one of Congress' principal objectives in enacting the MDA. In order to advance the other—promoting innovation in medical device technology—Congress established special rules governing devices developed for investigational use and rare conditions, *see* 21 U.S.C. §§ 360j(g), 360j(m), and authorized the FDA to enter into research and development contracts. *Id.* § 360j(k). More important, for present purposes, Congress explicitly preempted all state requirements with respect to medical devices "different from, or in addition to" the requirements established under the MDA. 21 U.S.C. § 360k(a)(1).[9] As discussed next, this express preemption provision is critical to Congress' effort to promote the development of new, improved, and *safer* medical devices.

II. SUBJECTING MEDICAL DEVICE MANUFACTURERS TO LIABILITY UNDER THE PATCHWORK OF STATE TORT LAW REGIMES WOULD STIFLE INNOVATION IN MEDICAL DEVICE TECHNOLOGY AND DRIVE EXISTING, FDA-CLEARED PRODUCTS FROM THE MARKETPLACE TO THE DETRIMENT OF PATIENT CARE.

1. As noted, medical device technology currently is experiencing an unprecedented period of growth. In the past fifty years, medical device technology—together with

[9] The MDA's preemption provision provides:

> Except as provided in subsection (b) * * * no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. [21 U.S.C. § 360k(a).]

Subsection (b) permits States to apply for an exemption from subsection (a)'s express preemption provision. *Id.* § 360k(b). That exemption is not implicated in this case.

medical science as a whole—has advanced at an exponential rate. Recent breakthroughs in medical device technology have vastly improved the quality of patient care in this country and have enabled Americans to live longer, healthier, and more productive lives. These advances have not come about by accident. They are the product of scientific ingenuity, numerous incremental steps in product development, and the allocation of vast private and public resources for research and development.

The medical device industry in the United States is a highly research-intensive, competitive industry comprised of small, relatively young, start-up companies. *See Hearings on Medical Device Safety, supra*, at 73; S. Rep. No. 33, *supra*, at 18. Because of the time and expense required to bring new or improved medical devices to market, most medical device firms are—at least early on—dependent upon venture capital financing. One recent study estimated that on average $10 to $20 million is required to bring a medical device from laboratory to market. *See Reforming the FDA: Hearing Before the Subcomm. on Health and Environment of the House Comm. on Commerce*, 104th Cong., 2d Sess., 1996 WL 5508897, at 3 (Feb. 27, 1996) [hereinafter *Hearing on Reforming the FDA*] (statement of John K. Clarke, director of the National Venture Capital Association). At the same time, there are enormous entrepreneurial risks associated with bringing a new medical device to market—including securing patent protection—and, in many cases, a new device will have a market lifespan of only about two to three years. *See id.*; *infra* at 19.

In 1994 alone, venture capitalists poured almost $500 million into medical device firms across the country. 1996 WL 5508897 at 2. This "seed" capital is critical to the vitality of the medical device industry. But it is far from abundant. In fact, Price Waterhouse recently reported that many small and emerging medical device companies in this country are extremely short of funds and are experiencing serious difficulties raising additional financing. *Id.* at 4. As venture capitalists seek higher and more secure returns, funding medical device firms has become a

riskier and less attractive investment option. *Id.* Yet capital investment is critical to the development of the next generation of medical devices. *See Trends in Venture Capital Funding for the Medical Device Industry* 3 (Health Care Technology Inst. Mar. 1994).

2. Exposing medical device manufacturers to state law products liability actions for alleged manufacturing, labeling, or design defects in federally-cleared devices will jeopardize the availability of that capital and have precisely the effect that Congress sought to prevent in enacting the MDA: it will stunt research and development efforts in the medical device industry and thereby stifle the development of new, improved, and safer products. But that is not all. Subjecting medical device manufacturers to state products liability laws also will cause manufacturers of existing, FDA-cleared medical devices to pull their products from the market. The real losers in this scenario are not the medical device manufacturers, but the patients who deserve access to safe, state-of-the-art medical care and the healthcare providers who wish to secure that for them.

One of the overriding concerns of private firms and individuals in the medical products market is liability under state tort law regimes.[10] This concern stems pri-

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[10] *See, e.g., Health Care Liability Reform and Quality Assurance Act of 1995, Hearing on S. 454 Before the Senate Comm. on Labor and Human Resources*, 104th Cong., 1st Sess. 38 (1995) (statement of Thomas Scully, President and CEO of the Federation of American Health Systems); *Entrepreneurship in America: Loosening the Government Noose on Small Business, Field Hearing Before the Senate Comm. on Small Business*, 104th Cong., 1st Sess. 111 (1995) (statement of E.R. Pickard, Chairman and CEO, Sofamor Danek Group, Inc.); *Product Liability: Hearing Before the Subcomm. on Technology and Competitiveness of the House Comm. on Science, Space, and Technology*, 102d Cong., 2d Sess. 115 (1992) [hereinafter *Hearing on Product Liability*] (statement of Dane Miller, Ph.D., President and CEO of Biomet, Inc.); *cf. Product Liability Fairness Act: Hearings on S. 640 Before the Subcomm. on Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 102d Cong., 1st Sess. 55 (1991) (statement of Michael Belletire, Office of the Governor, State of Illinois) (discuss-

marily from two well-recognized—and unsettling—features of the current products liability regimes in this country: products liability can be—and with perhaps increasing frequency is—crippling for businesses hauled into state court before juries, and yet the likelihood and extent of that liability is almost impossible to predict in a fashion that would enable businesses to regulate their conduct so as reasonably to avoid it.

Punitive damages awards "run wild" in state courts today. *Pacific Mut. Life Ins. Co.* v. *Haslip*, 499 U.S. 1, 18 (1991). *See generally* Richard Neely, *The Product Liability Mess: How Business Can Be Rescued From the Politics of State Court* (1988). These awards can permanently hobble a company in one fell swoop, and yet they are often "wholly unpredictable" and may "bear[] no necessary relation to the harm caused." *Haslip*, 499 U.S. at 12 (internal quotation marks and citation omitted). *See also TXO Production Corp.* v. *Alliance Resources Corp.*, 113 S. Ct. 2711, 2728-31 (1993) (O'Connor, J., dissenting). Moreover, in many medical products liability actions, the juries that decide businesses' fate lack the scientific expertise necessary to comprehend and resolve the complex factual issues on which liability typically hinges. *See generally* Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 Tex. L. Rev. 1 (1995); Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1 (1993).

Confounding the fear and uncertainty engendered by the specter of "sky's the limit" punitive damages awards is the patchwork of state products liability regimes imposing different—and sometimes conflicting—rules on manufacturers. As one commentator has observed:

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ing companies' reluctance to produce certain pharmaceutical products because of liability concerns). *See generally The Liability Maze: The Impact of Liability Law on Safety and Innovation* (Peter W. Huber and Robert E. Litan eds. 1991) [hereinafter *Liability Maze*].

> America's diversity of *court systems* leads to a diversity of *law systems* because American judges, like their English predecessors, have extensive lawmaking powers. And because each separate court system is administratively independent, each can generate eccentric judge-made law at odds with the statutory and judge-made law of other jurisdictions. Whole fields of American law, such as contracts and torts, are creatures of court decisions rather than legislative enactments. * * * Ironically, then, although business is increasingly national in nature, most of the law that governs business is parochial state tort, contract, or property law that not only guides decisions in local state courts, but also binds local federal judges when they are called upon to decide lawsuits based on state law between citizens of different states. [Neely, *supra*, at 31.]

There are of course fifty-one different state tort law systems in this country, including the District of Columbia's. The "rules" imposed by these systems not only vary from one State to another, they differ in a critical respect from those established by federal regulatory schemes: they are imposed in a retrospective—rather than prospective—fashion.

These and related products liability concerns are real and very much on the minds of medical device manufacturers today. Indeed, one need only consider the current plight of Dow Corning Corp. For several decades, Dow Corning manufactured and marketed silicone-gel breast implants with FDA authorization. Less than one percent of Dow Corning's total revenue was derived from the sale of implant-grade silicones and silicone-gel breast implants. Today the company has been forced into Chapter 11 and is struggling to stay afloat after being hit with a "blizzard" of products liability actions by silicone-gel breast implant recipients who claim to have developed various connective-tissue disorders. The company has sought—but been

denied—the opportunity to consolidate these actions and to refer the entire matter to an independent panel of scientific experts. Numerous epidemiological, statistical, and scientific studies, moreover, have discredited plaintiffs lawyers' theories that silicone-gel breast implants are the cause of their clients' affliction. Nevertheless, breast implant litigation has forced Dow Corning and other manufacturers to the brink of elimination. *See Truth, Justice & Implants*, Wall St. J., Feb. 26, 1996, at A12; Trisha Gura, *Implant Debate to Cripple Innovation?: Liability Fears May Impede Testing, Limit Supplies*, Chi. Trib., Mar. 13, 1995, at C1; David S. Hilzenrath *et al., Surviving the Breast Implant Siege*, Wash. Post, June 24, 1994, at F1.[11]

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[11] The FDA impaneled two blue-ribbon advisory panels to examine whether silicone-gel breast implants are unsafe. Neither panel found any causal link between these implants and serious illness. In response to public concerns sparked largely by the mushrooming breast implant litigation, however, the FDA issued a "temporary" moratorium in 1992 on the use of silicone-gel breast implants except for major reconstructive surgery in limited circumstances. Since then, numerous epidemiological studies have refuted plaintiffs lawyers' claims that silicone-gel breast implants are unsafe. The latest study—the largest to date—was conducted by researchers at the Harvard Medical School and was based on data collected from 395,543 women health professionals. The study ruled out the possibility that silicone-gel breast implants pose "large risks of connective-tissue diseases," and found that any added risk posed by these implants is so small that "it will be difficult to distinguish reliably between a small hazard and no hazard" at all. Charles H. Hennekens *et al., Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals: A Retrospective Cohort Study*, 275 J. Am. Med. Ass'n 616, 621 (1996). This study supports the results of earlier studies—including a 1995 Harvard Medical School study and a 1994 Mayo Clinic study—finding no association between silicone-gel breast implants and connective-tissue diseases. *See id.* at 620 (discussing Jorge Sanchez-Guerrero *et al., Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 New Eng. J. Med. 1666 (1995); Sherine E. Gabriel *et al., Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 New Eng. J. Med. 1697 (1994)). Nevertheless, despite the overwhelming—and growing—scientific evidence that silicone-gel breast implants are safe, these implants have been withdrawn from the marketplace because of liability concerns and no longer are available medical options for millions of American women and their physicians.

3. Fear of excessive and unpredictable state products liability causes many private firms simply to choose to stay out of the medical device industry altogether. Equally harmful from the standpoint of the long-term prospects of the medical device industry, such liability discourages already skittish venture capitalists from investing in medical device manufacturing companies. In an industry in which it can take several years—and several million dollars—to develop a product that must still pass an elaborate FDA review process before it may be marketed, liability concerns can—and with increasing frequency do—tip the balance in favor of putting one's capital investment into more conventional industries. As a result, many potentially life-saving products have not been developed—and today are not being developed—to the detriment of patient care.

As the American Medical Association (AMA) reported in one recent study.

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks. [AMA, *Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (June 1988)].[12]

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[12] Numerous commentators have recognized this growing problem as well. *See, e.g.*, Susan Bartlett Foote, *Managing the Medical Arms Race: Public Policy and Medical Device Innovation*. 149 (1992); *Liability Maze, supra*, at 334-356; Richard J. Mahoney, *Product*

It is of course difficult to quantify the stifling effect of liability concerns on the development of new medical products because it is impossible to say what is *not* being invented in medical laboratories across the country today. Nevertheless, it has been reported, for example, that liability concerns have had an inhibiting effect on the development of a vaccine for the AIDS virus. *See* Martin J. Hatlie *et al.*, *Health Care Liability: Reform in a Changing Environment*, in *State Civil Justice Reform* 47 (Roger Clegg ed. 1994); *Hearing on Product Liability*, *supra*, at 10 (statement of Rep. Rowland).[13] Liability concerns also reportedly have stunted the development of certain birth control products. *See* W. Kip Viscusi, *Reforming Products Liability* 66 (1991); Malcolm Gladwell, *U.S. Firms Abandoning Birth Control Industry in Wake of Lawsuits*, Wash. Post, May 1, 1988, at H1, col. 1.

Liability and Punitive Damages Laws Stifle Creativity and Innovation, Introduction to Jacqueline R. Denning, *et al.*, *Pernicious Ideas and Costly Consequences: The Intellectual Roots of the Tort Crisis* ix-x (Nat'l Legal Center for the Pub. Interest 1990); and authorities discussed *infra* at 18-19. *See also* U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, OTA-H-522, at 170 (Feb. 1993) ("Evidence drawn from the experiences of particular products or from interviews with industry executives indicates liability may inhibit or preclude R&D or marketing of reproductive-related vaccines and products").

[13] Fear of excessive liability in developing and marketing an AIDS vaccine is particularly well-founded in light of the tradition of products liability suits that have been brought—and that are brought each year—against manufacturers of life-saving vaccines. *See* Peter W. Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 Colum. L. Rev. 277, 286-288 & n.49 (1985) (discussing suits brought against manufacturers of polio, swine flu, and whooping cough vaccines); *Liability Maze*, *supra*, at 341-345 (discussing suits brought against manufacturers of smallpox, measles, rubella, mumps, influenza, diphtheria, tetanus, hepatitis, meningococcal disease, and pneumococcal infection vaccines). Tragically, each year several children die from complications associated with receiving these vaccines. For all practical purposes, these deaths could be prevented only by pulling these FDA-cleared vaccines from the market. But of course millions of children are also inoculated each year from these historically crippling diseases without incident. Because of liability concerns, many manufacturers have pulled their vaccines from the market. In some cases, the cost of those vaccines that have remained on the market has increased a "hundredfold." *Brown* v. *Superior Court*, 751 P.2d 470, 479 (Cal. 1988).

Liability concerns not only inhibit major breakthroughs in medical science, they also prolong the equally important process by which incremental developments in medical products are made. In the medical device industry in particular, the development of new products can be an "evolutionary" rather than a "revolutionary" process. As one industry official put it:

> Progress usually comes through one small modification at a time. A doctor may use a device and realize that a minor modification will make it work better. He makes a suggestion, and a manufacturer develops a slightly different device. Later, the doctor realizes with another minor change, the device could be helpful for a slightly different indication or even a new procedure. And so it goes. The average lifespan of a medical device is very short (2 or 3 years). If one looks back ten years in the field of medicine and compares the devices of 1986 to current technology, he would conclude that we have made gigantic strides. And we have, but it is important to understand that, in most instances, these strides were made incrementally. One generation of devices replaced by another, and another. [*Hearing on Reforming the FDA*, *supra*, 1996 WL 5508917 at 3 (statement of Stephen L. Ferguson, COO of the Cook Group, Inc., the largest privately held medical device manufacturer in the world).]

As research and development efforts diminish, incremental improvements in product safety and effectiveness will become fewer and far between. Moreover, in the face of mounting liability concerns—and in the absence of any federal shield against state common law actions—manufacturers will become more reluctant to develop and market new and improved products. The quality of patient care will, as a result, suffer.

4. In addition to arresting the development of safer, more effective medical products, liability concerns also drive existing, FDA-cleared products from the marketplace. This can occur without any scientifically credible proof that the particular products are unsafe or ineffective. Moreover, in many cases, it is not only the product —but the manufacturer with it—that is driven from the market. In this fashion, subjecting medical device manufacturers to often excessive and unpredictable products liability under state law will not only forestall progress in the quality of patient care, but will actually cause the quality of patient care to regress as more and more products are withdrawn from the market.

The classic example involves the drug Bendectin. Bendectin is the only prescription drug cleared by the FDA for the treatment of nausea experienced by many women during pregnancy. It was successfully marketed worldwide by the Merrell Dow Company beginning in 1956, and has benefited almost two million women in the United States alone. Over time, several major products liability suits were filed against Merrell Dow (and other manufacturers of the drug) by women whose children were born with congenital defects. It has never been scientifically proven that Bendectin causes such defects. Moreover, the FDA continues to authorize the use of Bendectin by pregnant women today.[14] Nevertheless,

[14] As Judge Kozinski put it in his opinion on remand in the *Daubert* case:

> The FDA—an agency not known for its promiscuity in approving drugs—continues to approve Bendectin for use by pregnant women because 'available data do not demonstrate an association between birth defects and Bendectin.' *U.S. Dep't of Health and Human Services News*, No. P80-45 (Oct. 7, 1980). Every published study here and abroad—and there have been many—concludes that Bendectin is not a teratogen. In fact, apart from the small but determined group of scientists testifying on behalf of the Bendectin plaintiffs in this and many other cases, there doesn't appear to be a single scientist who has concluded that Bendectin causes limb reduction defects. [*Daubert* v. *Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1314 (9th Cir.) (citation omitted), *cert. denied*, 116 S. Ct. 189 (1995).]

Merrell Dow and other manufacturers have been forced to withdraw the drug from the market because of liability concerns. *See Liability Maze, supra,* at 337-341; Sanders, *supra*, at 1.

The same scenario is unfolding today in the case of silicone-gel breast implants. *See supra* at 15-16. But, in the medical device industry, this phenomenon has taken on a new, even more alarming dimension: *suppliers* of the materials necessary to make literally thousands of life-saving medical devices—*e.g.*, silicone, teflon, polyester, and polyurethane—are withdrawing from the medical device market for fear of being dragged into products liability actions brought against the manufacturers of medical devices in which their materials are used. *See Hearing on Reforming the FDA, supra,* 1996 WL 5508917 at 3 (statement of Stephen L. Ferguson); Frederick D. Baker, *Effects of Products Liability on Bulk Suppliers of Biomaterials*, 50 Food & Drug L.J. 455 (1995) [hereinafter *Bulk Suppliers*]. In terms of cost-benefit analysis, the risk of potential liability under state products liability laws—however slight in the case of a bulk supplier—far outweighs the relatively insignificant pecuniary benefits of remaining in this discrete market.[15]

For example, polyurethane is used to make pacemakers. Each year Dow Chemical (Dow) sells massive amounts of polyurethane to American industry at large, including —unwittingly, in some cases—to medical device manufacturers. Dow's sales of this compound to pacemaker

[15] Courts generally do not impose products liability on bulk suppliers of materials that are used in medical devices, provided that (1) the material has many industrial uses (beyond the medical device field), (2) the supplier has no specialized knowledge of how a particular buyer intends to use the product, and (3) the buyer substantially alters the material to create a new product. *See Bulk Suppliers, supra,* at 455. Nevertheless, when a supplier is aware that its materials are being used in medical devices, it may be subjected to liability under state products liability laws. *See id.* at 456-458 (chronicling recent cases in which suppliers of silicone, polyethylene, and teflon used in medical devices have been exposed to liability under state law).

manufacturers represent less than one-half of one percent of its total annual sales. Revenues from these sales do not begin to cover even the costs of *defending* against lawsuits brought against pacemaker manufacturers in which it is joined as a co-defendant. As a result, Dow has cut its polyurethane sales to medical device manufacturers. Again, in economic terms, the decision for companies facing such liability is straightforward. The result, however, is devastating for patients requiring FDA-cleared medical devices that depend on such materials. *See* Barnaby J. Feder, *Implant Industry Is Facing Cutback by Top Suppliers: Giants Like Du Pont and Dow Fear They'll Be Drawn into Product Liability Suits*, N.Y. Times, Apr. 24, 1994, at A1.[16]

5. For these principal reasons, it is clear that subjecting medical device manufacturers to state products liability laws for marketing federally-cleared devices would

[16] The same thing is happening today with respect to silicone. In addition to breast implants, silicone is used in manufacturing implantable catheters, pacemaker leads, and artificial fingers and toes. It also has been used to make implantable "shunts" that have been used with tremendous success in preventing brain damage and death in children born with hydrocephalus. Yet the sale of silicone to medical device manufacturers represents only a tiny fraction of major silicone producers' total sales. And, as a result of the liability crisis caused by the breast implant litigation, many silicone manufacturers are withdrawing their product from the medical device and supply market altogether. *See Implant Debate to Cripple Innovation?: Liability Fears May Impede Testing, Limit Supplies, supra*, at C1. *See also* Carol Gentry, *Lifesavers Casualty of Silicone Debate*, St. Petersburg Times, Jan. 31, 1995, at 1A (noting that Du Pont recently notified medical device manufacturers that it would no longer sell to them critical synthetic materials used in making artificial blood vessels and heart valves).

Since much of the recent flowering of medical device innovation is based on the availability of new biomaterials, this development is particularly troubling. Indeed, Congress itself has taken note of this problem and has proposed legislation to ensure the availability of critical biomaterials such as silicone. *See Bulk Suppliers, supra*, at 459 (discussing the proposed Biomaterials Access Assurance Act of 1995).

defeat the MDA's statutory aims of promoting innovation in medical device technology and thereby fostering the development of new, improved, and safer medical devices to enhance the quality of patient care. There is no need for this Court to stretch the language or import of the MDA to ensure that state products liability laws do not have this debilitating effect on the MDA's regulatory scheme. Congress itself ensured that this would not occur by expressly preempting any state requirement with respect to medical devices that is "different from, or in addition to" the requirements established under the MDA. 21 U.S.C. § 360k(a)(1). As discussed next, under this Court's precedents, that express preemption provision must be given its natural—and intended—effect.

III. TO GIVE FULL EFFECT TO THE REGULATORY SCHEME ESTABLISHED BY THE MDA, THIS COURT SHOULD HOLD THAT STATE COMMON LAW CLAIMS BROUGHT AGAINST MANUFACTURERS OF FDA-CLEARED MEDICAL DEVICES ARE PREEMPTED.

1. The touchstone of this Court's preemption analysis is congressional intent. *See New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995). Congress' intent to preempt state law may be explicitly stated in a statute's text or implied from either the structure and purpose of an act or the fact that compliance with both federal and state law would be impossible. *See English* v. *General Elec. Co.*, 496 U.S. 72, 78-79 (1990). In order to give effect to Congress' intent in enacting the MDA and its 1990 amendments—to ensure the safety and effectiveness of medical devices and at the same time to promote innovation in medical device technology—this Court should hold that state common law claims for alleged manufacturing, labeling, or design defects in FDA-cleared devices are preempted.

2. To reach this conclusion, this Court need go no further than the MDA's express preemption provision. As

noted, that provision bars States from imposing with respect to medical devices "*any* requirement * * * which is different from, or in addition to, any requirement" established under the MDA. 21 U.S.C. § 360k(a) (emphasis added). *See supra* note 9. Congress intended Section 360k as a "general prohibition on non-Federal regulation" of medical devices, H.R. Rep. No. 853, *supra*, at 42, which, as discussed, was perfectly consistent with its efforts under the MDA to foster innovation in medical device technology. Under any plain reading, Section 360k requires preemption of state common law claims for alleged device manufacturing, labeling, or design defects.

Common law liability rules, just like positive enactments, impose requirements on medical device manufacturers. *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 515-516 (1992) (plurality). That much is manifest from this case alone. If successful, respondents/cross-petitioners' negligent design claim would subject Medtronic to a state law *duty* to redesign its pacemaker lead. *Cf. International Paper Co.* v. *Ouellette*, 479 U.S. 481, 495 (1987). Under the theory of respondents/cross-petitioners' case, that "requirement" is necessary to ensure the safety and effectiveness of the device at issue. But this requirement is "different from" and "in addition to" the requirements contained in the federal regulatory scheme.

As Judge Posner explained in a similar context:

> The theory underlying the complaint is that the design of the [device] was not sufficiently safe and effective to allow it to be used on human beings. This theory sets up a direct collision with federal policy. The FDA decided, whether rightly or wrongly, but pursuant to regulations the validity of which the plaintiff does not question, that the [device] could be sold subject * * * to [certain] requirements * * *. The plaintiff wishes in the name of state tort law to impose additional requirements—namely that the [device] have had a design that it lacked—and this engrafting of additional requirements relating to

> safety and effectiveness is forbidden by the preemption provision in the [MDA]. [*Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992).]

As detailed in petitioner's brief, subjecting Medtronic and other medical device manufacturers to state common law liability rules would conflict with numerous safety and effectiveness requirements established by the MDA and accompanying regulations. This includes those requirements established by the 510(k) process pursuant to which Medtronic obtained FDA authorization to market its pacemaker lead. *See* Pet. Br. at 18-36, 44-46. As discussed, that process is, like the PMA process, aimed at ensuring device safety and effectiveness. *See supra* at 9-10 & n.6. Moreover, once a device is cleared for marketing, a manufacturer is "for all intents and purposes * * * required to continue to design, manufacture, and label the device as proposed in its original 510(k) Notification." *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392, 399-400 (4th Cir.), *petition for cert. filed*, No. 95-1010 (Dec. 22, 1995). Permitting respondents/cross-petitioners to recover on any component of their state law action would flout those federal requirements and impose on Medtronic a duty to alter its manufacturing process, label, or device design that is wholly absent from the current federal regulatory scheme.

There is no basis for concluding, as did the court below, that Congress intended to insulate medical device manufacturers from some types of state products liability claims —*i.e.*, those predicated on alleged manufacturing or labeling defects—but not others—*i.e.*, those based on alleged design defects. As discussed, there are specific federal safety and effectiveness requirements governing device manufacturing, labeling, *and* design. *See supra* at 9-10. Moreover, permitting some common law tort claims to proceed against medical device manufacturers but not others would be flatly inconsistent with Congress' intent to encourage innovation in medical device technology,

because it would trigger the same liability concerns discussed above. *Cf. English* v. *General Elec. Co.*, 496 U.S. at 86 (it "would be odd, if not irrational" to conclude that Congress intended to preempt one set of state law tort claims under the Energy Reorganization Act but not others).

Congress intended for Section 360k to be given its natural effect. As discussed in the preceding section, it had important reasons for doing so. But even so, Congress did not categorically rule out the imposition of new or different state requirements in all instances. To the contrary, Congress established a specific mechanism by which States could obtain an exemption from the MDA's express preemption provision in order to impose "more stringent" requirements on medical device manufacturers necessitated by "compelling local conditions." 21 U.S.C. § 360k(b).[17] That Congress legislated this narrow exemption to Section 360k's express preemption provision provides all the more reason for this Court not to imply an additional—wholly unsupported—exemption for state products liability claims. *See Leatherman* v. *Tarrant County Narcotics Intelligence & Coordination Unit*, 113 S. Ct. 1160, 1163 (1993) ("[*e*]*xpressio unius est exclusio alterius*").

3. Giving effect to Congress' intent to preempt state common law actions under the MDA will not open the door to increased calls for preemption under other federal statutes. Federal preemption is singularly appropriate in this case: there is an express preemption provision requiring displacement of any state requirements "different from, or in addition to" the requirements established under the federal scheme; in enacting that federal scheme, Congress clearly and repeatedly expressed its intent to advance certain statutory aims; and permitting state common law

[17] Since 1976, the FDA has granted fifteen States and the District of Columbia permission to impose additional requirements on medical device manufacturers under this provision. *See* Pet. Br. at 5 n.3.

actions to proceed in the face of this congressional intent would significantly undermine—if not entirely defeat—those statutory aims.

Nor will honoring Congress' intent threaten the safety or effectiveness of medical devices marketed for public use. As discussed below, in enacting the MDA Congress established a detailed regulatory scheme by which medical devices may enter the marketplace. There are several different routes a device may take, but all roads pass through the FDA and no Class III device may be marketed without prior FDA authorization. The level of FDA scrutiny and expertise is unmatched at the state—as well as international—level. Moreover, if and when a device reaches the marketplace, the manufacturer remains under continuing federal oversight and reporting requirements. At the same time, the FDA possesses broad authority to protect and ensure device safety and effectiveness if any problems arise. *See supra* at 9-10.

To be sure, medical devices—like all man-made devices—malfunction. No federal regulatory or state tort law regime can prevent that. But in enacting the MDA, Congress made a calculated decision to rely on federal regulation and FDA oversight and expertise—not lay juries charged with applying state products liability laws—to protect and promote medical device safety and effectiveness. Congress did so, moreover, in order to ensure that it did not stifle innovation in medical device technology and thus inhibit the development of new, improved, and safer devices to the detriment of patient care. Experience teaches that this was a wise decision. In any event, it is not for this Court to upset the balance that Congress has struck.

CONCLUSION

For the foregoing reasons, and for those set forth in petitioner Medtronic's brief, the judgment below should be reversed insofar as it permits plaintiffs to maintain state common law claims against medical device manufacturers for alleged defects in FDA-cleared devices.

Respectfully submitted,

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v.

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BRIEF OF THE AMERICAN INSURANCE ASSOCIATION, THE AMERICAN TORT REFORM ASSOCIATION, AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iv
STATEMENT OF INTEREST	1
INTRODUCTION AND SUMMARY OF ARGUMENT	3
ARGUMENT	5
I. CONGRESS HARMONIZED NATIONAL AND LOCAL INTERESTS BY PROVIDING A RULEMAKING PROCESS TO PERMIT EXEMPTIONS FROM PREEMPTION	5
A. The MDA Permits States To Petition The FDA For Exemptions From Preemption Through The Rulemaking Process	5
B. The Rulemaking Process Applies To State Tort Requirements	9
II. STATE TORT LAW REQUIREMENTS, UNLESS FOUND APPROPRIATE FOR EXEMPTION FROM PREEMPTION BY THE FDA, WOULD UNDERMINE UNIFORMITY AND IMPERIL THE AVAILABILITY AND SAFETY OF MEDICAL DEVICES	13
III. FINDING PREEMPTION IS CONSISTENT WITH CONGRESSIONAL INTENT AND IS GOOD PUBLIC POLICY	17
CONCLUSION	20

TABLE OF AUTHORITIES

CASES — Page

Artiglio v. Superior Court (McGhan Medical Corp.), 22 Cal. App. 4th 1388, 27 Cal. Rptr. 2d 589 (1994) 14
Berger v. Personal Prods., Inc., 797 P.2d 1148 (Wash. 1990), *cert. denied*, 499 U.S. 961 (1991) .. 10
Bristol-Meyers Co. v. Gonzalez, 561 S.W.2d 801 (Tex. 1978) 14
Brown v. Superior Court (Abbott Laboratories), 751 P.2d 470 (Cal. 1988) 14, 18
Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 9
Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) 15
Duvall v. Bristol-Myers Squibb Co., 65 F.3d 392 (4th Cir. 1995) 3
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English v. Mentor Corp., 67 F.3d 477 (3d Cir. 1995) 3
Flanagan v. State, 625 So. 2d 827 (Fla. 1993) 16
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TABLE OF AUTHORITIES—Continued

Page

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Parklane Hosiery Co., Inc. v. Shore, 439 U.S. 322 (1979) 10
Pienger v. Alza Corp., 11 Cal. App. 4th 349, 13 Cal. Rptr. 2d 811 (1992) 14
People v. Leahy, 882 P.2d 321 (Cal. 1994) 16
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Schultz v. State, 664 A.2d 60 (Md. 1995) 16
Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995) 4

STATUTES

21 U.S.C. §§ 301 *et seq.* (1988 & Supp. 1993) 2
21 U.S.C. §§ 351, 352 (1988) 5
21 U.S.C. §§ 360c *et seq.* (1988 & Supp. 1993) 2, 3
21 U.S.C. §§ 360k(a), (b) (1988) ..... *passim*
28 U.S.C. §§ 1346(b), 2671 *et seq.* 11
Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 26050 *et seq.* (repealed) 6

REGULATIONS

21 C.F.R. § 807.81(a)(3)(i) 15
21 C.F.R. Part 808, subpart C 7
21 C.F.R. §§ 808.1(b), (c) 13
21 C.F.R. § 808.5 11
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	Page
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	Page
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59 Fed. Reg. 26,352-26,353 (1994)	12

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BRIEF OF THE AMERICAN INSURANCE ASSOCIATION, THE AMERICAN TORT REFORM ASSOCIATION, AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

STATEMENT OF INTEREST

Amici represent casualty insurers and manufacturers of health care products.[1] This case is of interest and particular importance to the *amici* because its outcome will likely affect the quality, availability, and cost of health care for every American. In terms of both costs and effectiveness, sophisticated medical devices have become

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[1] Pursuant to Rule 37, letters of consent have been filed with the Clerk of the Court.

a central feature of modern medicine. Congress recognized that rational regulation of complex medical devices requires a considerable degree of national uniformity. The Medical Device Amendments of 1976 ("MDA")[2] to the Federal Food, Drug, and Cosmetic Act of 1938[3] were designed to achieve that uniformity, while preserving tort remedies in appropriate situations approved by the Food and Drug Administration ("FDA") through rulemaking. *See* 21 U.S.C. § 360k(b) (1988).

The American Insurance Association ("AIA") is a national trade organization representing over 270 companies writing casualty/property insurance in every state and jurisdiction of the United States. These companies provide 27 percent of all casualty/property insurance underwritten in the United States. AIA companies are affiliated with 79,000 independent insurance agents nationwide.

The American Tort Reform Association ("ATRA"), founded in 1986, is a broad-based, bipartisan coalition of more than 300 businesses, corporations, municipalities, associations, and professional firms who have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance and predictability in civil litigation.

The National Association of Manufacturers ("NAM") is the nation's oldest and largest broad-based industrial trade association. Its nearly 14,000 member companies and subsidiaries, including approximately 10,000 small manufacturers, are in every state and produce about 85 percent of U.S. manufactured goods. Through its member companies and affiliated associations, the NAM represents every industrial sector and more than 18 million employees, and as such, the Court's ruling in this case could have significant ramifications beyond the subject litigation.

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[2] 21 U.S.C. §§ 360c *et seq.* (1988 & Supp. 1993).

[3] 21 U.S.C. §§ 301 *et seq.* (1988 & Supp. 1993).

INTRODUCTION AND SUMMARY OF ARGUMENT

In the Medical Device Amendments of 1976, Congress sought to avoid conflicting rules,[4] improve safety,[5] encourage innovation,[6] and assure the continued availability of affordable, safe and effective medical devices without denying compensation to injured persons.

Congress implemented its intent through the MDA's general preemption provision, 21 U.S.C. § 360k(a) (1988), and the provision authorizing states to petition the FDA to impose additional requirements. *See* 21 U.S.C. § 360k(b) (1988). These provisions, as enacted, do not imply that state tort law is foreclosed or that individuals who are injured because of defective medical devices are left without a remedy. To the contrary, the MDA specifically authorizes states to adopt tort remedies in medical device cases after the FDA has determined, following rulemaking, that the additional requirements that would be imposed by state tort law neither undermine the safety or effectiveness of the device nor undermine the availability of the device in any state, including the state proposing the new requirement. *See* 21 U.S.C. § 360k(b) (1988).[7]

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[4] *See* Sen. Rep. No. 33, 94th Cong., 2d Sess. 3 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. *See also Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir. 1994); *King v. Collagen Corp.*, 983 F.2d 1130, 1137-38 (1st Cir.), *cert. denied*, 114 U.S. 84 (1993).

[5] *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (*1976*); 21 U.S.C. § 360c (1988 and Supp. 1995). *See also Duvall v. Bristol-Myers Squibb Co.*, 65 F.3d 392, 395 (4th Cir. 1995) (citing *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir. 1944)); *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995).

[6] *See generally* National Academy of Sciences, *New Medical Devices: Invention, Development, And Use* 73 (National Academy Press, 1988) (observing that subjecting medical devices to both federal regulation through the FDA and state regulation through state court requirements produces "serious distortions").

[7] In addition, an injured party may receive restitution through the criminal process. The First Circuit Court of Appeals recently

Congress, when it enacted the MDA, pictured a system where national regulation would predominate, and distortions brought about by local regulation would be controlled and minimized.[8] Congress intended to achieve these goals by preempting state and local requirements that could burden interstate commerce by threatening the availability of medical devices.[9]

The preemption and petition provisions of the MDA permit the divergent regimes of federal regulation and state common law to be rationally harmonized. The MDA preserves the ability of injured persons to receive compensation [10] and the need for "uniform, nationwide standards" [11] governing medical devices. Indeed, only

noted that a court finding noncompliance with FDA requirements may order payment of restitution as part of criminal sanctions against a manufacturer. *See Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 30 (1st Cir. 1995).

[8] Concern that states and local subdivisions would impose their own requirements on sophisticated medical devices was a significant factor in Congress's desire to extend federal preemption. The legislative history of the MDA reveals that:

> The Committee recognizes that if a substantial number of different requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened. For this reason the reported bill prescribes a general rule that no State or political subdivision thereof may establish or continue in effect any requirement with respect to a device for human use which is different from, or in addition to, any requirement made applicable to such device.

H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976).

[9] *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 12, 45 (1976).

[10] *See* 21 U.S.C. § 360k(b) (1988).

[11] *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995). *See also* Sen. Rep. No. 295, 94th Cong., 2d Sess. 1071 (1976) (Congress "wants to be sure that the FDA has the proper authority to regulate the process so that Americans are not put at risk from the use of unsafe and ineffective medical devices"); H.R. Rep. No. 853, 94th Cong., 2d Sess. 15 (1976). *See generally* American Law

through the preemption and petition provisions can these goals be simultaneously achieved.

ARGUMENT

I. CONGRESS HARMONIZED NATIONAL AND LOCAL INTERESTS BY PROVIDING A RULEMAKING PROCESS TO PERMIT EXEMPTIONS FROM PREEMPTION.

A. The MDA Permits States To Petition The FDA For Exemptions From Preemption Through The Rulemaking Process.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938 represent a carefully considered congressional response to the burgeoning area of medical device technology. Prior to the enactment of the MDA, there was no federal premarket review, although there were general federal controls regarding adulterated and misbranded devices.[12] The MDA thus federalized within the FDA what had largely been within the province of individual state regulators, in the

Institute, 2 *Enterprise Responsibility For Personal Injury—Reporters' Study* 106 (1991) ("Federal statutes providing for nationally uniform product regulation present a strong case for recognizing preemption because of the limited state interest in imposing more stringent standards through state tort law and the potential adverse effect of tort liability on investment, innovation, and international competitiveness.")

[12] The Federal Food, Drug, and Cosmetic Act of 1938 drew a sharp distinction between drugs and medical devices. While devices were subject to the Act's adulteration and misbranding prescriptions, *see* 21 U.S.C. §§ 351, 352 (1988), the Act's premarket review provisions did not apply to devices. The 1976 MDA gave the FDA comprehensive regulatory authority over medical devices for the first time. In 1990, Congress amended the MDA by enacting the Safe Medical Devices Act of 1990 ("SMDA"). The SMDA contained several provisions designed to provide the FDA with greater regulatory authority over devices. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 13 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6306.

expectation of improving safety and effectiveness by developing national standards and requirements.[13]

As a necessary corollary to the new concentration of authority within the FDA, Congress expressly preempted all state and local requirements that are "different from, or in addition to, any requirement applicable under [the MDA]." 21 U.S.C. § 360k(a)(1) (1988). Congress also sought to accommodate the diverse needs of individual states, including those expressed through state tort litigation, in a rational manner consistent with the goal of achieving national uniformity in the distribution of medical devices. Congress, therefore, created an "escape valve" from the MDA's expansive express preemption provision which permits states to petition the FDA for leave to adopt their own standards. The "petition provision" of the MDA, 21 U.S.C. § 360k(b) (1988), states:

> Upon application of a State or a political subdivision thereof, the Secretary [of Health and Human Services] may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed by such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
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> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
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> (2) the requirement—
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> (A) is required by compelling local conditions, and

[13] Some states, such as California, had long before created a full-fledged food and drug administration to regulate medical devices sold within the state. *See generally* the Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 26050 *et seq.* The Sherman Food, Drug, and Cosmetic Law has since been repealed.

> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k(b) (1988).

This petition provision rebuts the claim that Congress intended to permit state courts to alter federal labeling, design, or manufacturing requirements for complex medical devices and renders the Lohr's position anomalous. Under 21 U.S.C. § 360k(b), a state which, after months of detailed study and scores of public hearings, determines that a particular requirement is necessary for a medical device marketed within its borders must still proceed to file an application with the FDA authorizing the state to adopt the new requirement. Under the Lohr's reasoning, however, a court can in essence impose the very same requirement without any need to bring the matter to the FDA's attention. There is no basis for believing that Congress intended such a dichotomy between state legislative or administrative requirements and state tort law requirements.

The petition provision has been invoked by numerous states seeking exemption from preemption.[14] The final rule issued by the FDA with respect to the applications of Massachusetts and Rhode Island for preemption exemptions for their state hearing aid requirements is particularly instructive.[15] Initially, the laws of both states required mandatory audiological evaluation prior to purchase of hearing aids. Nevertheless, after receiving extensive comments and "reviewing the conflicting information in the public record," the FDA concluded "that

[14] *See, e.g.*, 45 Fed. Reg. 67,321 (1980); 45 Fed. Reg. 67,325 (1980) (applications for exemption regarding state hearing aid requirements by twenty states and the District of Columbia). A complete list of exemptions granted to state and local governments is contained at 21 C.F.R. Part 808, subpart C.

[15] *See* 45 Fed. Reg. 67,326 (1980).

audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids." [16] The agency further concluded that the requirement of mandatory audiological evaluation "could increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification." [17]

The formal rulemaking process set forth in the MDA permits the FDA the opportunity, after hearing from experts and all interested parties, to make an informed determination as to whether there should be an exemption from preemption. Through this process, the FDA can balance the need for national uniformity against other legitimate interests in a fair and informed manner.[18] Congress intended this rulemaking process, not the judicial process, to be the primary mechanism for balancing competing interests and determining when exemption from

[16] 45 Fed. Reg. 67,329 (1980).

[17] 45 Fed. Reg. 67,329 (1980). The final rule issued by the FDA with respect to California's application for a blanket exemption for its own pre-existing medical device requirements (The Sherman Food, Drug, and Cosmetic Act) is also instructive. *See* 45 Fed. Reg. 67,321 (1980). In issuing the final rule, the FDA carefully reviewed California's requirements, held a public hearing, and received extensive comments. Ultimately, the FDA exempted some of California's requirements from preemption and denied exemption to others. Notably, during the course of rulemaking the FDA reversed its position on one proposed exemption based on comments it received, and ultimately concluded that California had not adequately addressed the issue of whether its requirements concerning color additives might unduly burden interstate commerce. 45 Fed. Reg. 67,321 ¶ 10 (1980). *See also* 21 C.F.R. § 808.20(c)(7) (providing that an application for exemption should include information of how public health may be benefitted and how interstate commerce may be affected if an exemption is granted).

[18] Congress understood that rulemaking is ideally suited for balancing competing interests and developing policy that can have widespread effects. *See generally* Stephen G. Breyer & Richard B. Stewart, *Administrative Law and Regulatory Policy* 472 (2d ed. 1985).

federal labeling, design, or manufacturing requirements for complex medical devices is appropriate.[19]

B. The Rulemaking Process Applies To State Tort Requirements.

Congress also intended the MDA's rulemaking process to apply to state court requirements. This interpretation is fully consistent with this Court's holding in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), which correctly made clear that state tort judgments can constitute "requirements" within the meaning of a federal preemption statute.[20] Following *Cipollone*, courts interpreting the MDA have held that "21 U.S.C. § 360k(a)'s preemption of state 'requirement[s]' 'different from, or in addition to' those of the MDA is broad enough to include state common law causes of action." [21]

[19] There is judicial review of MDA rulemaking. *See, e.g., Massachusetts v. Hayes*, 691 F.2d 57 (1st Cir. 1982). *See generally* Paul Hyman, *Litigated Cases under the Medical Device Amendments of 1976*, 40 Food Drug Cosm. L.J. 85 (1986).

[20] *See id.* at 521 (plurality op. of Stevens, J., Rehnquist, C.J., and White and O'Connor, J.J. ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations in the form of common law rules.") *See also id.* at 547-48 (Scalia, J., joined by Thomas J., concurring in the judgment in part and dissenting in part).

[21] *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1275 (7th Cir. 1995), *petition for cert. filed* Feb. 20, 1996 (No. 95-1323). *See also* Victor E. Schwartz, Robert P. Charrow & Mark A. Behrens, *Following the Supreme Court's Analysis in Cipollone, Courts Are Finding Broad Preemption in Sophisticated Medical Device Tort Litigation*, 17 J. Prods. & Toxics Liab. 31 (1995). The view that Congress intended the preemption provision to apply to court decisions finds support in the fact that Congress chose not to revisit the express preemption provision of the MDA when it enacted the 1990 SMDA, despite the fact that *every* reported decision to address the issue of preemption of state tort law failure to warn claims held the MDA to be preemptive. *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, *reh'g denied*, 873 F.2d 297

Thus, for example, a lawsuit based on an allegedly inadequate design or warning system, (*e.g.*, there was a light but not a bell or whistle) could impose an additional design or labeling requirement on a device whose design or labeling has been approved or cleared by the FDA.[22] It is therefore preempted, absent a successful exemption petition by the state, just as a state statute which requires particular warning language or a particular warning system would be preempted.

The rulemaking process mandated by Congress to exempt state court "requirements" from the MDA's pre-

(5th Cir. 1989); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988); *Berger v. Personal Prods., Inc.*, 797 P.2d 1148 (Wash. 1990), *cert. denied*, 499 U.S. 961 (1991).

[22] It should be noted that in many jurisdictions—including Arizona, Colorado, Connecticut, the District of Columbia, Delaware, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Missouri, New Mexico, New York, North Carolina, Pennsylvania, South Carolina, Utah and Wisconsin—a judgment in a single case can be given statewide effect through the application of offensive collateral estoppel principles. By invoking the doctrine, a plaintiff who was not a party to a prior action can seek to establish a claim against a party who had been a party to the prior action. In so doing ,a defendant may be barred from asserting a defense that the defendant has previously litigated and lost against a different plaintiff. *See Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 331 (1979). Notably, trial courts in these jurisdictions have wide discretion over whether the use of offensive collateral estoppel is appropriate in a particular case. *See id.*

The impact of offensive assertions of collateral estoppel has been dramatic in the pharmaceutical area. For example, in *Rubel v. Eli Lilly and Co.*, 681 F. Supp. 151 (S.D.N.Y. 1987), *recon. denied*, 1995 WL 92303 (Mar. 7, 1995), the court held that prior verdicts in cases involving diethylstilbestrol ("DES") manufacturer Eli Lilly were not so inconsistent as to preclude use of offensive collateral estoppel to bar manufacturer from relitigating issue of negligent testing. Through the ripple effects created through offensive collateral estoppel, this single judgment potentially had an impact far beyond the four corners of the case, despite subsequent decisions precluding use of offensive collateral estoppel on related—and arguably identical—issues.

emptive effect accommodates state tort law litigation.[23] States are likely to file petitions where requested to do so by injured state citizens.[24] Moreover, the state's application for an exemption need not be limited to a single case. The state can petition to impose a new requirement, *e.g.*, clearer warning language or stronger design features, for a class or classes of devices.[25] Just as with a statutory requirement, the state would have to provide information demonstrating that the judicially imposed requirement would be more stringent than the FDA's requirement or, alternatively, if the requirement is needed due to compelling local conditions, that compliance with the requirement would not cause the device to be in violation of any applicable requirement under the Act. *See* 21 C.F.R. § 808.20(c)(4). In addition, the state would have to provide information "on how the public health may be benefitted and how interstate commerce

[23] The "escape valve" from preemption that Congress created in the MDA is somewhat analogous to another congressional statute addressing liability law: the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b), 2671 *et seq.* (1995). Before Congress enacted the FTCA, the federal government was immune from civil tort suits. *See* W. Page Keeton, *Prosser and Keeton on the Law of Torts* § 131 (5th ed. 1984). Congress enacted the FTCA to allow recovery against the United States for certain types of conduct, but it was careful to impose strong procedures to protect the government from runaway liability. For example, FTCA cases are decided by a federal judge, not a jury, punitive damages are not available, the plaintiff's attorney's contingent fee is subject to express regulation (below the general "market rate") and prior to filing suit, the plaintiff must exhaust administrative remedies.

[24] FDA regulations expressly provide for an advisory opinion. *See* 21 C.F.R. § 808.5. They also provide that a state can request expedited consideration of its exemption application if "litigation regarding applicabilty of the requirement is pending." 21 C.F.R. § 808.20(d).

[25] Page 24 of the Lohr's brief misconstrues 21 U.S.C. § 360k(b) (1988) when it suggests that states would have to petition the FDA for exemptions for individual plaintiffs on a case-by-case basis. Nothing in the statute requires such a procedure.

may be affected, if an exemption is granted." 21 C.F.R. § 808.20(c)(7).

The FDA, after a hearing and a comment period, would first determine whether the proposed new requirement met one of the two statutory bases for exemption. If it did, the FDA still would have discretion to deny the exemption. *See, e.g., Massachusetts v. Hayes*, 691 F.2d 57, 60 (1st Cir. 1982).[26] It could choose to evaluate all the relevant factors bearing on the public health, including whether the requirement enhances the safety and effectiveness of the device,[27] and whether the requirement is so costly that it is likely to reduce the availability of the device.[28] Congress appropriately decided that such evaluation is better done by the FDA through its rulemaking process than by courts and lay juries through the judicial process.

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[26] The plain lannguage of 21 U.S.C. § 360k(b) (1988) emphasizes the discretion vested in the FDA, providing that "Upon application of a State . . . the Secretary *may* . . . exempt [from preemption]" (emphasis supplied).

[27] *See* 45 Fed. Reg. 67,321 (1980), where the FDA, in considering a state's exemption application for hearing aids, refused to approve an exemption for an existing state requirement after finding that "an audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids."

[28] *See* 43 Fed. Reg. 18661, 18664 (1978) ("[T]he Commissioner [of Food and Drugs] may not grant an exemption if he determines that the granting of an exemption would not be in the best interest of the public health, taking into account the potential effect on the public health of granting or denying an exemption, *e.g.*, additional cost to consumer, availability of needed products, etc.") The cost to manufacturers and end users of new regulatory requirements and its impact on availability have always been key factors in FDA decision-making. *See* 59 Fed. Reg. 26,352-26,353 (1994) (in establishing new standards for electrode leads, the FDA solicited comments on the "[c]ost to manufacturers and the user community to convert to protected electrode lead wires").

II. STATE TORT LAW REQUIREMENTS, UNLESS FOUND APPROPRIATE FOR EXEMPTION FROM PREEMPTION BY THE FDA, WOULD UNDERMINE UNIFORMITY AND IMPERIL THE AVAILABILITY AND SAFETY OF MEDICAL DEVICES.

Sophisticated medical devices differ from ordinary consumer goods: they are complex and frequently incorporate "cutting-edge" technologies; they are generally prescribed for use by physicians; and they offer substantial (and unique) benefits and involve inherent risks. As a result, Congress sought to, and in fact did, impose nationally uniform standards on medical devices which were intended to supplant the diverse, conflicting and often ineffectual procedures and requirements that various "states [had] established" for regulating devices. H.R. Rep. 853, 94th Cong., 2d Sess. 45 (1976). Congress expressly "recognize[d] that if a substantial number of differing requirements applicable to medical devices are imposed by jurisdictions other than the federal government, interstate commerce would be unduly burdened." *Id.* Congress also recognized that responsibility for developing these national standards should be left to trained professionals, *e.g.*, scientists, physicians and engineers, and understood that excessive, inappropriate, and erratic regulation would stifle innovation, jeopardize the availability of medical devices, and substantially increase health care costs.[29] The preemption and exemption provisions of the MDA were designed to ensure that any form of state requirement—whether by "statute, ordinance, regulation, or court decision," 21 C.F.R. § 808.1(b)—would not undermine these goals.

Nowhere is the potential for undermining Congress's intent as great as where medical device requirements are

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[29] *See* H.R. Rep. 853, 94th Cong., 2d Sess. 12 (1976) ("The Committee has developed a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions.")

set through state "tort regulation." Tort laws vary widely from state to state, and sometimes within states.[30] Indeed, state laws differ on even some of the most basic principles of product liability law.[31]

For example, in some states such as California, FDA premarket approval or clearance insulates a device manufacturer from a strict liability design defect claim.[32] In other states, such as Texas, however, FDA approval or clearance has little bearing on claims alleging strict products liability.[33] Thus, a jury in Texas, but not California,

[30] The variation in law from state to state increases uncertainty and costs without providing a corresponding benefit in the form of improved health or safety. *See generally* Jason Scott Johnson, *Uncertainty Chaos, and the Torts Process; An Economic Analysis of Legal Form*, 76 Cornell L. Rev. 341 (1991).

[31] *See Matter of Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1300 (7th Cir.) (Posner, J.), *cert. denied sub nom. Grady v. Rhone-Poulenc Rorer, Inc.*, 116 S. Ct. 184 (1995). *See generally* John Wade *et al., Prosser, Wade and Schwartz's Cases and Materials on Torts* 740 (9th ed. 1994) (describing various standards used by states to determine whether a product is "defective."); Victor E. Schwartz, *Comparative Negligence* app. b (3d ed. 1994) (setting forth diverse approaches taken by the states to address the issue of plaintiff fault and its effect on a defendant's liability).

[32] *See Artiglio v. Superior Court (McGhan Medical Corp.)*, 22 Cal. App. 4th 1388, 27 Cal. Rptr. 2d 589 (1994) (silicone gel breast implants); *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 13 Cal. Rptr. 2d 811 (1992) (IUDs) and *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 5 Cal. Rptr. 2d 377 (1992) (penile prostheses), *opinion modified* (Mar. 17, 1992). The policy engine driving these cases, which was first set forth in *Brown v. Superior Court (Abbott Laboratories)*, 751 P.2d 470, 479 (Cal. 1988), is that medical devices, like pharmaceuticals, are incapable of being made absolutely safe, but are so important and beneficial to society that liability law should not be permitted to discourage their innovation or distribution.

[33] *See Bristol-Meyers Co. v. Gonzalez*, 561 S.W.2d 801 (Tex. 1978) (affirming finding that warning as to drug's dangers was not adequate, as a matter of law, simply because it complied with FDA labeling requirements, and upholding six figure verdict based on inadequate warning). Unfortunately, in most jurisdictions, courts

might hold a manufacturer of a lifesaving device strictly liable for an allegedly inadequate design, obligating the manufacturer to change the device's design or doom itself to certain, repeated damages awards, including punitive damages. Ironically, the redesigned device could *not* be sold without prior FDA clearance or approval.[34] Until the lengthy FDA clearance or approval process is completed, the lifesaving device would not be available to persons in need.

In addition to the substantive tort law, the pertinent rules of evidence also vary widely from state to state. These differences are particularly troublesome where a court or jury is asked to render a scientific or technical judgment.[35] In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2795 (1993), this Court sought to ensure that federal courts would be guided only by scientific and technical evidence that had been "derived by the scientific method." While many states have em-

may find that a medical device's design is defective, its warning inadequate, or its labeling incomplete even if the FDA has mandated the precise language and has determined that the product is safe and effective. *See* Restatement (Third) of the law of Torts: Products Liability § 7(b) (Tent. Draft No. 2, Mar. 13, 1995); *Merrell Dow Pharmaceuticals, Inc. v. Oxendine*, 649 A.2d 825, 829 (D.C.App. 1994) (FDA finding that drug is "safe and effective," ". . . is a term of art, not a legal conclusion for state tort law purposes").

[34] Once the FDA determines that a device is "substantially equivalent" and clears the device for marketing, the manufacturer cannot change the device design or construction in a manner "that could significantly affect the safety or effectiveness of the device" without an additional 510(k) review by the FDA. *See* 21 C.F.R. § 807.81(a)(3)(i).

[35] Concern over the ability of lay factfinders fully to comprehend complex scientific principles is not new. *See* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 54 (1902) (noting paradox in asking jurors to judge which of two expert statements is true, when the experts are called precisely because the jury is incompetent in that area).

braced *Daubert*, others have declined.[36] As a result, decisions about the design, labeling, or manufacture of complicated medical devices may be influenced by aberrant opinions not derived in accordance with the scientific method.[37]

Furthermore, regulation by state tort law, without exemption by the FDA through the formal rulemaking process, guarantees that requirements for complex technologies, which are often understood only by experienced and knowledgeable experts, will be shaped by well-intended lay jurors or judges who may lack the foundation necessary to balance the competing concerns which are involved in developing policy decisions affecting the national health. Scrutiny of federal labeling, design, or manufacturing requirements for complex medical devices by courts and lay persons would also be inconsistent with the Congress's and the FDA's tradition of relying

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[36] *See, e.g., Schultz v. State*, 664 A.2d 60, 64 (Md. 1995) (test based on *Frye* standard is still "the standard utilized in Maryland"); *People v. Leahy*, 882 P.2d 321, 323 (Cal. 1994) (California court refused to substantively revise pre-*Daubert* test); *Flanagan v. State*, 625 So. 2d 827, 829 n.2 (Fla. 1993) ("Florida continues to adhere to the *Frye* test for the admissibility of scientific opinions"). Some federal courts have even refused to apply the Federal Rules of Evidence in diversity cases if those rules would undermine a state's substantive law. *See, e.g., Habecker v. Clark Equip. Co.*, 36 F.3d 278 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1313 (1995).

[37] *See, e.g., Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir.) (overturning $75 million punitive damages award), *cert. denied*, 498 U.S. 950 (1990); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318 (1986) (imposing punishment against the manufacturer of the Sabin oral polio vaccine, because the company had not used a version of polio vaccine that had been abandoned for general use in the United States for over two decades. The Kansas Supreme Court, by the slimmest of margins, one vote, reversed an $8 million punitive damages verdict. One vote the other way and children in Kansas could have lost access to the Sabin polio vaccine), *aff'd*, 758 P.2d 206 (Kan. 1988).

heavily on expert scientific review before permitting a newly designed medical device to be marketed.[38]

III. FINDING PREEMPTION IS CONSISTENT WITH CONGRESSIONAL INTENT AND IS GOOD PUBLIC POLICY.

Open-ended tort regulation would produce unwanted and socially undesirable state requirements on medical device manufacturers, which would distort Congress's intent.[39] Without question, under the specter of unlimited and unpredictable tort judgments, "manufacturers might be reluctant to undertake research programs to develop certain devices that would prove beneficial or to distribute others that are available to be marketed, because of fear of large adverse monetary judgments."[40] Further, the

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[38] Indeed, Congress focused on the need to tap into "scientific expertise" in regulating medical devises. *See generally* H.R. Rep. No. 853, 94th Cong., 2d Sess. 10-12 (1976); Sen. Rep. No. 33, 94th Cong., 2d Sess. 6-11 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1076-80.

[39] According to a report published by the National Academy of Sciences, the purposes of FDA regulation and tort litigation are remarkably different and indeed often contradictory. *See generally* National Academy of Sciences, *New Medical Devices: Invention, Development, and Use* 73-74 (National Academy Press, 1988). FDA regulation is intended to assure the public health through the continued availability of new, safe, and effective medical products, and thus necessarily involves a balancing of overall risks and benefits. On the other hand, injured parties with product liability lawsuits are not directly concerned with public policy, with the effects of the decision-making on the public at large, or with the impact that a decision will have on the future availability or cost of a product; their primary goal is to seek compensation. *Id.*

[40] Victor E. Schwartz, Robert P. Charrow & Mark A. Behrens, *Following the Supreme Court's Analysis in Cipollone, Courts Are Finding Broad Preemption in Sophisticated Medical Device Tort Litigation*, 17 J. Prods. & Toxics Liab. 31, 44 (1995). *See generally* Steven Garber, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* xxxii (1993) (RAND study recommending compliance with FDA regulations as a complete defense to liability for drugs and sophisticated medical devices on public

additional expense of insuring against such liability—assuming insurance would be available—could place the cost of many beneficial devices beyond the reach of those who need them.[41]

A finding that state tort laws are not subject to the preemption and exemption provisions of the MDA will undermine the availability of medical devices.[42] This is aptly illustrated by recent litigation involving suppliers of raw materials used to manufacture medical devices. These suppliers are not subject to the preemption provision of the MDA; therefore, a look at their situation provides a window into how the future of medical device availability may look in an environment of "no preemption."

Recently, liability concerns have caused suppliers of raw materials and component parts to medical implant manufacturers to cease supplying these critical base materials, jeopardizing the availability of implantable medical devices necessary to the lives of millions of Americans. A 1994 study by Aronoff Associates concluded that there are significant numbers of raw materials that are "at risk" of shortages in the immediate future.[43] Suppliers have found that the risks and costs of responding to litigation

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policy grounds); Peter Huber & Robert Litan, *The Liability Maze: The Impact of Liability Law on Safety and Innovation* 7 (1991) (reporting on American Medical Association study finding that "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance").

[41] *See generally Brown v. Superior Court (Abbott Laboratories)*, 751 P.2d 470, 479 (Cal. 1988).

[42] *See generally* Peter Huber, *Safety And The Second Best: The Hazards Of Public Risk Management In The Courts*, 85 Colum. L. Rev. 277, 337 (1985) ("[I]t is insane to snuff out with legal paper those who would light the candle of a cure. . . . It is out of the nettle, danger, that we pluck the flower, safety").

[43] *See* Aronoff Associates, *Market Study: Biomaterials Supply for Permanent Medical Implants* (Mar. 1994).

related to medical implants far exceeds potential sales revenues, even though courts are not finding suppliers liable.[44]

The biomaterials availability crisis is already having an adverse impact on consumers. Consider the case of Peggy Phillips, a survivor of two episodes of Sudden Death Syndrome and the recipient of an Automatic Implantable Cardioverter Defibrillator device. On April 4, 1995, Ms. Phillips testified before the Consumer Affairs, Foreign Commerce and Tourism Subcommittee of the Senate Committee on Commerce, Science and Transportation that, as a patient with a lifesaving medical implant, her worry is that such devices "may not be available to those who need them," because the "threat of liability suits" is causing suppliers of raw materials to pull out of the medical device market.[45]

Ms. Phillips shared with the Subcommittee her experience on a recent panel discussion sponsored by the American Institute for Medical and Biological Engineering in which representatives of medical science and the device industry put "tort law on trial." A woman in the audience wanted to know if the threatened shortage of biomaterials was serious. "A chill ran up my spine," Ms. Phillips testified, "when the panelists could not guarantee that [the battery used to power my Automatic Implantable Cardioverter Defibrillator device] would be available in the United States because of the threatening shortage of raw materials used in the devices resulting from product liability concerns."[46]

In light of the express congressional purposes in enacting the MDA, regulation by tort verdict—unchecked by

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[44] *See* Edward M. Mansfield, *Reflections on Current Limits on Component and Raw Material Supplier Liability and the Proposed Third Restatement*, 84 Ky. L.J. 221, 235-37 (1995-96).

[45] Sen. Rep. No. 104-69, 104th Cong., 1st Sess., at 52 (1995).

[46] *See id.*

the FDA through the formal rulemaking process—would create an unacceptable risk of extending the biomaterials supply crisis to the entire field of complex medical devices.

CONCLUSION

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938 were designed to achieve national uniformity, avoid conflicting state and local rules, and encourage innovation, while preserving tort remedies in appropriate situations approved by the FDA through rulemaking and assuring the continued availability of safe and effective and affordable medical devices. Permitting courts to impose duplicative or even conflicting device requirements, without requiring the State to successfully petition the FDA for an exemption from the preemption provision of the MDA, would violate the letter and spirit of Congress when it enacted the MDA and would introduce serious distortions into the device market that may adversely affect the public health.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writs of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit

BRIEF *AMICI CURIAE* OF AMERICAN ASSOCIATION OF RETIRED PERSONS, CONSUMERS UNION, CONSUMER FEDERATION OF AMERICA, NATIONAL WOMEN'S HEALTH NETWORK, COMMAND TRUST NETWORK AND VALV IN SUPPORT OF RESPONDENTS/CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

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40pp

TABLE OF CONTENTS

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 1

ARGUMENT 3

I. THE VAGUE PREEMPTION PROVISION IN THE MEDICAL DEVICE AMENDMENTS CANNOT OVERCOME THE STRONG PRESUMPTION AGAINST PREEMPTING THE TYPE OF STATE LAW AT ISSUE HERE 3

II. THE LIMITED POWERS THE MDA CONFERRED ON THE FOOD AND DRUG ADMINISTRATION INDICATE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE LAW TORT ACTIONS 6

A. The Primary Purpose of the MDA Was to Enhance Protection of Public Health and Safety 6

B. Federal Authority Under the MDA Did Not and Does Not Provide For Many of the Means of Protection Available Through the Tort System 7

1. Limits on Scrutiny of Medical Devices 8

2. Limits on FDA Enforcement Authority 13

3. Lack of Damage Remedies 16

C. Inadequate Funding of the FDA from the 94th Congress to the Present Has Further Weakened the Capacity of the Agency to Ensure Health and Safety 18

III. THE MANY CASES OF SEVERE INJURY CAUSED BY MEDICAL DEVICES SINCE 1976 SHOW THE LIMITED NATURE OF THE FDA'S AUTHORITY AND UNDERSCORE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE TORT SUITS 20

A. The Tort System Has Functioned As Congress Envisioned When It Passed the MDA: As a Necessary Complement To Federal Authority 20

B. The Bjork-Shiley Heart Valve 21

C. The Vitek Jaw Implant 23

D. Playtex Super-Absorbent Tampons 23

E. The Airco Ventilator 24

F. Orcolon Eye Gel 24

G. Silicone Breast Implants 25

H. Pedicle Screws 26

IV. A FINDING OF PREEMPTION HERE WOULD OPEN THE FLOODGATES FOR DEMANDS FOR JUDICIALLY-CREATED TORT IMMUNITY . . 27

CONCLUSION 29

TABLE OF AUTHORITIES

CASES **Page**

Airco, Inc. v. Simmons First National Bank,
638 S.W.2d 660 (Ark. 1982) 24

Bailey v. Johnson,
48 F.3d 965 (6th Cir. 1995) 16

Bowling v. Pfizer,
143 F.R.D. 141 (S.D. Ohio 1992) 22

Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992) 17, 27

Duvall v. Bristol-Myers-Squibb Co.,
65 F.3d 392 (4th Cir. 1995),
petition for cert. filed,
Dec. 22, 1995, No. 95-1010 27

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496 U.S. 72 (1990) 5

English v. Mentor Corp.,
67 F.3d 477 (3d Cir. 1995),
petition for cert. filed,
Dec. 26, 1995, No. 95-1034 27

Hawaiian Airlines, Inc. v. Norris,
114 S. Ct. 2239 (1994) 4

Hillsborough County v. Automated Medical Laboratories,
471 U.S. 707 (1985) 5

King v. Collagen Corp.,
983 F.2d 1130 (1st Cir.),
cert. denied, 114 S. Ct. 84 (1993) 27

Maryland v. Louisiana,
451 U.S. 725 (1981) 5

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cert. denied, 116 S. Ct. 67 (1995) 22

Moe v. MTD Products, Inc.,
73 F.3d 179 (8th Cir. 1995) 29

Moore v. Kimberly-Clark Corp.,
867 F.2d 243 (5th Cir. 1989) 15

New York Telephone Co. v. New York State Department of Labor,
440 U.S. 519 (1979) 5

O'Gilvie v. International Playtex, Inc.,
821 F.2d 1438 (10th Cir. 1987),
cert. denied, 486 U.S. 1032 (1988) 23

In Re: Orthopedic Bone Screw Product Liability Litigation,
M.D.L. Docket No. 1014 (E.D.Pa.) 26

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464 U.S. 238 (1984) 5, 16

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961 F.2d 1330 (7th Cir.),
cert. denied, 113 S. Ct. 327 (1992) 15

Stamps v. Collagen Corp.,
984 F.2d 1416 (5th Cir.),
cert. denied, 114 S. Ct. 86 (1993) 27

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865 F. Supp. 37 (D.Mass. 1994),
aff'd, 63 F.3d 25 (1st Cir. 1995),
petition for cert. filed,
Feb. 16, 1996, No. 95-1321 11

United States v. C.R. Bard, Inc.,
848 F. Supp. 287 (D. Mass. 1994) 10

CONSTITUTIONAL PROVISIONS, STATUTES & REGULATIONS

Consumer Product Safety Act,
15 U.S.C. § 2075 28

Federal Hazardous Substances Act,
15 U.S.C. § 1261 note 28

Federal Rule of Civil Procedure 26(b)(1) 13

Federal Rule of Civil Procedure 37 13

Medical Device Amendments of 1976,
P.L. No. 94-295, 90 Stat. 539 (1976)
(codified at 21 U.S.C. § 360c *et seq.*) . . . . . *passim*

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21 U.S.C. § 360c(f)(1) 12

21 U.S.C. § 360e(b)(1)(A) 11

21 U.S.C. § 360e(c)(1) 9

21 U.S.C. § 360e(c)(2) 9

21 U.S.C. § 360h(b)(1) 13

21 U.S.C. § 360j(h)(1) 9

21 U.S.C. § 360j(i) 9

21 U.S.C. §360k(a) 4, 28

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P.L. No. 101-629, 104 Stat. 4511 . . . . . 9, 14

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21 U.S.C. § 333(g)(2)(A) 14

21 U.S.C § 360h(e) 14

21 U.S.C. § 360h(e)(1)(A) 14

21 U.S.C. § 360h(e)(1)(B) 14

21 U.S.C. § 360*l* 14

U.S. Const. art. VI, cl. 2 4

21 C.F.R. § 807.100 (b) 12

LEGISLATIVE MATERIALS

121 Cong. Rec. 10688 (1975) 7

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before the Senate Comm. on Labor
and Human Resources, Apr. 6, 1995 . . . . . 12, 18

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Government Reform and Oversight, Aug. 1, 1995 25

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May 2, 1995 8

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STATEMENT OF INTEREST

With the written consent of the parties, reflected in letters on file with the Clerk, the American Association of Retired Persons, Consumers Union, Consumer Federation of America, the National Women's Health Network, Command Trust Network, and VALV respectfully submit this brief as *amici curiae*, pursuant to Rule 37 of the Rules of this Court.

Amici are non-profit organizations concerned with public health and safety. Each believes that the public cannot be adequately protected against dangerous medical devices in the absence of effective state law tort remedies.

The American Association of Retired Persons is a membership organization of 33 million persons age 50 and over; it seeks to enhance the quality of life for older persons by promoting independence, dignity and purpose; sponsors research on aging; provides educational programs, publications, volunteer opportunities and member benefits; and represents the concerns of older Americans before government bodies. Consumers Union is a membership organization, chartered in 1936, which provides consumers with information, education and counsel about goods, services, health and personal finance; initiates and cooperates with individual and group efforts to maintain and enhance the quality of life for consumers; and publishes *Consumer Reports* magazine, with paid circulation of approximately 5 million. Consumer Federation of America is an association of some 240 pro-consumer groups, with a combined membership of 50 million people; it was founded in 1968 to advance the consumer interest through advocacy and education. The National Women's Health Network is a membership group which advocates for better federal health policies for women and works to ensure that safe drugs, devices and medical procedures are available to all women; it is supported by 15,000 individual and 300 organizational members representing over 500,000 people. Command Trust Network is an international informational clearinghouse for women who have questions about breast implants. VALV is a support group for recipients of the Bjork-Shiley convexo-concave heart valve. *See* part III.B, *infra*.

SUMMARY OF ARGUMENT

Medtronic, Inc., asks this Court to hold, based on the vague preemption provision in the Medical Device Amendments of 1976,

P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c *et seq.*) ("MDA" or "the Act"), that Congress meant to grant manufacturers immunity from state tort liability with respect to medical devices. If this Court is to remain faithful to long-standing principles of federalism and separation of powers, it must reject this utterly implausible proposition, aimed, as one industry representative has put it, at obtaining "tort reform" from the bench "without a single vote from this Congress." Had the 94th Congress in 1976 truly sought to effect the radical transformation of the law claimed by Medtronic — and to do so in an apparently arbitrary way, affecting some products (medical devices), though not others (such as food and drugs) — surely it would have debated the issue and explained its bold step, just as intense discussion surrounds "tort reform" proposals in Congress today. But there is no evidence of any such debate or remarks in 1976, because there was never any such intention.

In fact, Congress's clear goal in enacting the MDA was not to "reform" tort law to suit industry but rather to enhance protection of public health and safety. Congress crafted a limited regulatory regime that could only have been effective in achieving that goal if it was a complement to — not a substitute for — state tort remedies.

The MDA was and is wholly inadequate as a replacement for tort law. The MDA does not provide the Food and Drug Administration ("FDA") with sufficient means and incentives to obtain information about medical devices and their manufacturers, either before or after devices go on the market. Nor does the MDA provide damages for people injured by dangerous devices. Nor, as enacted in 1976, did the Act provide for civil penalties to punish violators or give the FDA sufficient authority to force the recall of harmful devices. In addition, the MDA includes mechanisms — the so-called grandfathering and substantial equivalence provisions — permitting the sale of devices never examined by the federal government for safety or effectiveness — and about 99 percent of medical devices enter the market through these procedures. In sharp contrast, tort law provides broad discovery provisions that bring to light important product information; damages awards to deter and compensate for wrongful acts, as well as injunctive relief to stop them; and a mechanism by

which state authority may evaluate the safety and effectiveness of *any* medical device used on patients.

The Congress that enacted the MDA, as well as every subsequent Congress, has failed to fund the FDA at a level that might have permitted the agency to make adequate use of even the limited statutory powers it has. These funding decisions are further evidence that Congress never intended that FDA oversight would entirely supplant the tort system in dealing with medical devices.

The many deaths and serious injuries caused by devices the MDA regime has allowed on the market since 1976 show the limited nature of the Act's reach. In many cases, it has been the tort system, and not the MDA, that protected the public. Indeed, the tort system has functioned as Congress would have expected when it passed the MDA: as a necessary and cost-effective state law complement to the limited federal regime.

Finally, because the circumstances here present a very weak case for preemption, a ruling by this Court that the tort claims at issue are preempted could convince lower courts to hold that similar narrow preemption provisions in other federal consumer protection statutes, including the Consumer Product Safety Act and the Federal Hazardous Substances Act, bar state law tort claims as to the thousands of products regulated under those laws. The result would be a tumultuous gutting of the tort systems of the states and a dramatic restriction of the rights of injured persons — an outcome that the 94th Congress did not authorize or intend.

ARGUMENT

I. THE VAGUE PREEMPTION PROVISION IN THE MEDICAL DEVICE AMENDMENTS CANNOT OVERCOME THE STRONG PRESUMPTION AGAINST PREEMPTING THE TYPE OF STATE LAW AT ISSUE HERE

Jeff Kimbell, executive director of the Medical Device Manufacturers Association, has provided a candid assessment of what this lawsuit is about. "If the Supreme Court affirms the preemption," he told a trade publication, "it could go a long way toward achieving tort reform without a single vote from this

Congress or the next Congress." Hoffman, *Medical Device Liability Case; High Court's Ruling Likely to be Pivotal*, Business Insurance, Jan. 29, 1996, at 2. The phrase "tort reform" normally refers to hotly-contested *legislative* efforts, in statehouses and in the Congress, to alter common law tort doctrines. This case is the culmination of efforts by manufacturers to avoid the legislative process by persuading courts to weaken the tort system through strained readings of federal statutory provisions — to dramatically alter the relationship between consumers and alleged wrongdoers, as well as the relationship between the federal and state governments — without a single vote from any duly-elected legislator.[1]

The Lohrs claim that Lora Lohr was injured by a Medtronic Model 4011 pacemaker lead. Medtronic contends that the MDA preempts the Lohrs' Florida common law tort remedies. The company relies on a provision of the 1976 Act, 21 U.S.C. §360k(a), which bars states from "establish[ing] or continu[ing] in effect" with respect to any medical device "any requirement which is different from, or in addition to, any requirement" in the MDA, if that requirement concerns safety and effectiveness or is otherwise governed by the Act.

The principles of this Court's preemption jurisprudence and underlying principles of federalism and separation of powers require this Court to reject Medtronic's strained interpretation of the Act.

Whether a given state law is preempted pursuant to the Supremacy Clause of the Constitution, U.S. Const. art. VI, cl. 2, is a question of congressional intent. *Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994). However, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). The presumption against preemption is especially strong in this case for three reasons.

[1] Manufacturers have been able to achieve far less in Congress than they have under court decisions like the Eleventh Circuit's in this case. The "tort reform" bill passed by the House of Representatives in 1995 would eliminate punitive damages, but not compensatory damages, in suits arising from the use of medical devices that have been approved by the FDA. *See* 141 Cong. Rec. H2941-H2948 (Mar. 9, 1995); 141 Cong. Rec. H3027 (Mar. 10, 1995). The inclusion of this provision indicates that even the "tort reform"-minded House not only believes that all state tort remedies are available with respect to medical devices under current law but also intends, notwithstanding proposed broad changes in tort rules, that such suits continue.

First, the state law rules allegedly subject to preemption in this case — common law tort doctrines — are general rules of conduct, not requirements specifically directed at a particular industry. This Court's decisions "have consistently recognized that a congressional intent to deprive the states of their power to enforce general laws is more difficult to infer than an intent to preempt laws directed specifically at concerted activity." *New York Telephone Co. v. New York State Department of Labor*, 440 U.S. 519, 533 (1979) (plurality opinion).

Second, the challenged state law rules are in an area of traditional state concern — protecting public health and safety. *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 715 (1985). Where this traditional and particularly important state authority is at issue, this Court will not find preemption without evidence that preempting state law was "the clear and manifest purpose of Congress." *Id.*

Third, the federal statute involved provides no remedy of the type provided by the state law allegedly preempted — here, damages to compensate individuals for their injuries. In such circumstances, again, this Court has demanded strong proof of congressional intent to preempt. *See English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); part II.B.3, *infra*.

In light of these factors, this Court should resolve any doubts about the meaning of the federal enactment in favor of the parties arguing against preemption, the Lohrs. There should, in any case, be no serious doubts here. The Lohrs have amply demonstrated that nothing in the MDA provides justification for stripping the states of their historic authority to protect public health and safety by means of the common law.

This Court's requirement of clear and manifest indication of congressional intent to preempt prevents the kind of unwarranted usurpation of state law and individual rights urged by Medtronic. Had Congress made clear to the states that their power to enforce general laws with respect to a broad range of products was to be

so profoundly restricted, they might have used their influence in the political process to protect or restore their authority. Had Congress made clear to advocates for strong health and safety protections, such as *amici*, that it was acting to exempt thousands of potentially hazardous medical devices from the tort liability rules of the states, they would have worked to defeat the offending provisions. They would have done so precisely because the MDA fails to provide the protections and remedies that are available through tort law.

II. THE LIMITED POWERS THE MDA CONFERRED ON THE FOOD AND DRUG ADMINISTRATION INDICATE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE LAW TORT ACTIONS

A. The Primary Purpose of the MDA Was to Enhance Protection of Public Health and Safety

Congress enacted the MDA in 1976, at a time of widespread awareness that rapid advances in biomedical technologies posed not only great promise but also serious safety risks. A 1970 public report by a Nixon Administration commission, established to evaluate the need for greater federal regulation, documented some 10,000 injuries, including 751 fatalities, from medical devices over a ten-year period. These included deaths, miscarriages, birth defects and infections caused by the poorly-designed Dalkon Shield intrauterine device; eye injuries and vision loss from defective intraocular lenses; and deaths and injuries from defective pacemakers. *See* Cooper, *Device Legislation*, 26 Food Drug Cosm. L.J. 165 (1971).

Prior to enactment of the MDA, the FDA had virtually no power to regulate medical devices. The agency had authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") to seize adulterated or misbranded devices, but the process was difficult: The agency could not take action until after a device had been marketed, and it bore the burden of establishing that the device was unsafe or mislabeled. The only way to keep a dangerous device off the market in the first place was to convince a court to treat the device as a "drug." *See* H.R.Rep. 853, 94th Cong., 2d Sess. 8-10 (1976) ("House Report").

The MDA's legislative history demonstrates that the Act's primary purpose was to increase protection of health and safety by enhancing the FDA's authority to prevent the sale of dangerous and ineffective medical devices. *See* House Report, at 1-12; H.R. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 1 (1976); Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo.L.Rev. 895, 922 n.126 (1994) ("Any fair reading of the legislative history of the Medical Device Amendments will reveal that, except for a few passing references to the need to avoid slowing innovations in medical technology, the critical, and endlessly repeated, focus of congressional attention was to protect consumers from dangerous devices") (citations omitted). The principal Senate sponsor, Senator Kennedy, noted that the MDA "is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975).

Given the clear congressional goal of increasing public protection from the dangers of medical devices, it cannot be that Congress meant to strip the states of all of their traditional authority to allow individuals to seek recovery for personal injuries from such devices. In terms of health and safety protection, the MDA's statutory scheme would be a wholly inadequate substitute for the tort system.

B. Federal Authority Under the MDA Did Not and Does Not Provide For Many of the Means of Protection Available Through the Tort System

The common law tort systems of the states have long served crucial functions. Tort remedies allow injured victims to recover damages caused by negligent or intentional wrongdoing. Tort law punishes and deters improper business practices and thereby rewards responsible and ethical behavior in the marketplace. In addition, using the broad civil discovery rules, tort litigation has exposed misconduct and unsafe practices and alerted the media, the public, legislators and regulatory agencies to vital health and safety problems. The tort system has worked particularly well at protecting the public against harmful products, while at the same

time costing government, business and consumers remarkably little.[2] Tort law helps remove from the market products whose dangers are greater than their benefits and deters the sale of such products in the first place.

A Congress concerned about public safety could never have considered the MDA's limited regulatory scheme to be an adequate replacement for state tort systems. FDA powers under the statute do not come close to fulfilling the public protection functions that tort law provides.

1. Limits on Scrutiny of Medical Devices

In deciding whether the 94th Congress could have judged the MDA to be an adequate replacement for tort law in protecting the

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[2] Contrary to popular myth, product liability claims do not place major economic burdens on business or consumers. Actuary J. Robert Hunter, Federal Insurance Administrator in the Ford and Carter Administrations and later the Texas Insurance Commissioner, now studies liability and insurance issues for *amicus* Consumer Federation of America. In a 1995 report, he found that the total cost of product liability insurance premiums and other product liability costs in 1993 was only 19.9 cents for every $100 in retail sales; in the ten year period from 1984 to 1993, the cost was 26 cents per $100 dollars in sales. Hunter, *Product Liability Insurance Experience 1984-1993* (Consumer Federation of America, Mar. 1995). Hunter told a Senate committee, "The current system of product liability is an exceptional bargain for America: it serves as a deterrent to unsafe products in a free market way, with no bureaucratic regulation, it takes care of persons injured by unsafe products, and it costs remarkably little." Testimony of J. Robert Hunter before the Subcomm. on Admin. Oversight and the Courts of the Senate Comm. on the Judiciary, May 2, 1995. Similarly, a 1995 study by the Risk & Insurance Management Society, Inc., an organization of corporate and non-profit risk managers, and Tillinghast-Towers Perrin, a business consulting firm, found that the cost of "liability risk" — insuring against not only product liability but also other employment discrimination, shareholder suits and other claims — amounted to 25.5 cents for every $100 in revenue in 1994 (a 22 percent drop from the 1993 cost). A *Wall Street Journal* report on the study noted that its "findings are intriguing in light of the widely-held view that American employers are being held hostage by litigation." Wall Street Journal, Dec. 11, 1995, at B5, col. 1.

public against dangerous devices, consider one fact at the outset: Acting in a manner fully consistent with the requirements of the MDA, the FDA specifically evaluates only one percent of new medical devices for safety and effectiveness. And, as discussed below, even the scrutiny that that one percent receives under the Act has been insufficient to keep dangerous products off the market.

The MDA directed the FDA to place each medical device into one of three classes based on level of risk. Class I devices, simple medical tools like bandages, were subject only to general FDA controls applicable to all medical devices, such as labeling requirements and so-called good manufacturing practices. Class II devices, such as syringes and tampons, were, in addition, supposed to meet FDA performance standards.[3] The riskiest devices, such as intrauterine devices and pacemaker components like the one at issue in this case, were to be placed in Class III and, under the MDA, were eventually supposed to undergo a process called pre-market approval ("PMA").

PMA procedures, at least on their face, provide some safety assurance and public disclosure benefits. A manufacturer seeking pre-market approval must conduct both laboratory and clinical studies of the device and submit an application attesting to the device's safety and effectiveness. 21 U.S.C. § 360e(c)(1). The application is reviewed by an FDA panel, which meets in open session, and the agency must release transcripts of the panel meetings, excising only discussions of trade secrets. *Id.* §§ 360e(c)(2), 360j(i). When the FDA, after considering the panel's recommendations, issues its decision, the agency must publish a statement regarding the product's effectiveness and safety, including potential risks. *Id.* § 360j(h)(1). *See* Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J.L. & Tech. 1 (1989).

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[3] The FDA never implemented performance standards for devices, the result of which was that Class II devices were essentially subjected to no more stringent review than Class I devices. In the 1990 Safe Medical Devices Act, *see* part II.B.2, *infra*, Congress eliminated the requirement that the FDA issue performance standards as to each Class II device.

The MDA's PMA process, however, has severe limitations as a protector of public safety. First, it is never required with respect to Class I or Class II devices. Second, it does not impose specific requirements as to the design, manufacture or labeling of any given device. Third, by itself, it does nothing to monitor the safety of devices after they have entered the market.

In addition, the MDA's scheme for PMA review has allowed some remarkably hazardous products onto the market. Take, for example, the "Mini Profile" catheter, made by C.R. Bard, Inc. In May 1988, the FDA approved the catheter through the PMA process. The catheter was to be used in angioplasty, a procedure in which the device is threaded through a patient's body and inflated to clear clogged arteries leading to the heart. Subsequent investigation revealed that no later than February 1988, Bard executives knew that the catheter had a propensity to fail and that such failure could cause death. In March 1988, Bard filed a fraudulent, inaccurate statement with the FDA in support of its PMA application. From July through November 1988, Bard received at least 28 complaints from doctors and others about the Mini Profile's failure to deflate. Bard did not notify the FDA, and the agency apparently did not find out on its own. Bard continued to ship the catheter while launching a secret effort to redesign it.

In December 1988, Eunice Beavers, a resident of Missouri, died during an angioplasty procedure when a Mini Profile catheter failed to deflate, thus blocking her blood flow. Bessie Mae Robinson of Virginia had died in September 1988 under similar circumstances. Boston Globe, Apr. 2, 1994, Economy, at 12; Boston Globe, Oct. 31, 1993, Metro/Region, at 1.[4]

Federal authorities eventually learned of Bard's misconduct from a business competitor. In April 1994, U.S. District Judge Mark L. Wolf accepted an agreement under which the manufacturer pled guilty to 391 felony counts and agreed to pay $61 million in fines, an amount equal to the total revenues Bard

[4] Meanwhile, 50 patients had the tip of another Bard catheter, the B Probe, break off inside them during procedures, causing, in some cases, excruciating pain and permanent disability. Authorities later charged that Bard hid from the FDA knowledge that the tips tended to break. *Id.*

had earned on the catheter. *United States v. C.R. Bard, Inc.*, 848 F. Supp. 287 (D. Mass. 1994).

Although the legal system thus eventually punished Bard for its exceptionally egregious misconduct, FDA powers — even when the agency exercised its most stringent review, PMA — were insufficient to keep a dangerous device from entering the market or to detect or expose hazards promptly once it went into use. Nor did the federal statutory scheme provide a dime in compensation to victims, such as the survivors of Eunice Beavers, who saw their state tort claims dismissed on preemption grounds.[5]

The substantial weaknesses in the PMA process, however, are no match for the gross shortcomings, in terms of public protection, of the two provisions by which the MDA has permitted the vast majority of medical devices, including the pacemaker lead at issue in this case, to reach or remain on the market. First, a device in commercial distribution prior to the effective date of the 1976 MDA was "grandfathered" and did not have to go through the PMA process unless and until the FDA classified the device as Class III *and* issued a final regulation calling for PMA applications. *See* 21 U.S.C. §§ 360e(b)(1)(A), 351(f)(2)(B).

[5] The family of Eunice Beavers, along with other victims of the defective device, asked Judge Wolf to order restitution in the criminal proceeding. He declined, holding that it would be too time-consuming and complicated to litigate fault for injuries in connection with criminal sentencing. He added that civil suits were a much more appropriate means for redressing injuries because, in contrast to a criminal restitution proceeding, damages for pain and suffering and punitive damages might be available. 848 F. Supp. at 292-93.

Four months later, Judge Wolf himself dismissed the civil suit brought by the Beavers family. He concluded, based on First Circuit precedent brought to his attention by Bard, that their claims were preempted by the MDA. The First Circuit affirmed. *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37 (D.Mass. 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, Feb. 16, 1996, No. 95-1321.

The FDA did eventually issue a recall of the Mini-Profile catheter and imposed civil fines on Bard, but it did so under authorities Congress provided in 1990. *See* part II.B.2, *infra*. The 1976 MDA, the legislation that Medtronic contends preempted state tort law, did not allow for even these protections.

Second, under the so-called 510(k) procedure, a new device can enter the market promptly, without FDA safety review, if it is "substantially equivalent" to a "grandfathered" device or a substantially equivalent device already on the market, or if it is a Class I or Class II device. 21 U.S.C. § 360c(f)(1)(A). Because the 510(k) notification process is far less elaborate and far less expensive than the PMA application process, and because the FDA has yet to issue final PMA regulations for most Class III devices, 510(k) clearance has become the overwhelmingly dominant means of market entry: Notifications under section 510(k) account for 80 percent of Class III devices on the market and 99 percent of all medical device submissions. H.R. Rep. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307; Testimony of FDA Commissioner David A. Kessler before the Senate Comm. on Labor and Human Resources, Apr. 6, 1995.

The "grandfathering" and 510(k) procedures require no FDA evaluation of whether a device is safe or effective. *See* 21 U.S.C. § 360c(f)(1); 21 C.F.R. § 807.100 (b). The procedures also totally fail as means of providing public information about medical devices. The 510(k) process is "a black box, entirely shielded from ... public scrutiny." Leflar, 2 Harv. J.L. & Tech. at 34. There is no advisory panel, no reported record, no statement of reasons, and no opportunity provided by statute to challenge the marketing clearance administratively or in court. *Id.*

Although there is no evidence that the 94th Congress intended the 510(k) process to become the dominant means by which Class III medical devices would enter the market in the long term, Congress certainly had to expect a substantial transition period — while the agency worked to classify devices and review PMA applications — during which this process would play the central role and in which many grandfathered devices would remain on the market. Moreover, nothing in the 1976 Act imposed time tables for implementation of PMA requirements or otherwise prevented the FDA from relying indefinitely on 510(k) procedures to clear most devices, including Class III devices, for marketing. In light of the evidence documented by the Nixon Administration's 1970 report and the crisis over the Dalkon shield, it is wholly implausible that Congress, in the process of enacting a law aimed at increasing public protection, would have meant to abolish all tort remedies *immediately* on the effective date of the Act —

thereby leaving the public with virtually no protection, not even the modest requirements of the PMA process, for an indefinite period.

2. Limits on FDA Enforcement Authority

Even assuming that Congress intended a relatively rapid transition, after which the vast majority of Class III devices would be subject to pre-market approval, the MDA would still have lacked many of the important public protection benefits provided by the tort system with respect to any medical device.

First, again, under the MDA, pre-market approval procedures are never required for Class I and Class II devices.

Second, the 1976 Act did not provide the FDA with adequate authority to investigate industry practices. In particular, the 1976 Act did not provide, nor did prior law grant, subpoena power to the FDA to compel the disclosure of documents or the testimony of witnesses relating to medical devices. By contrast, the civil discovery rules that govern tort litigation in state and federal courts permit plaintiffs broad authority to obtain, by court order if necessary, records and other physical evidence as well as the appearance of witnesses. *See, e.g.*, Fed.R.Civ.P. 26(b)(1), 37.

Nor did the MDA, as enacted, establish effective procedures for monitoring FDA-approved medical devices *after* they had entered the market. *See* Leflar, 2 Harv. J.L. & Tech. at 78-82; Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 518-519 (1988). This shortcoming reduced substantially the MDA's effectiveness in deterring improper practices by manufacturers. The tort system, of course, operates precisely by providing such post-market scrutiny.

Nor did the 1976 Act give the FDA sufficient means to order the recall of a defective device. Although the Act provided the FDA with the technical authority to compel repair, replacement, or refund with respect to medical devices, 21 U.S.C. § 360h(b)(1), substantive and procedural hurdles written into the Act itself

prevented the agency from ever exercising this authority.[6] Nor did the 1976 Act authorize the FDA to impose civil penalties in order to deter and punish misconduct.

In its brief, Medtronic contends that "[u]nder the MDA, the FDA ... has broad enforcement power." Brief for Petitioner Medtronic at 6-7. Yet many of the FDA authorities that Medtronic cites to support that proposition are nowhere to be found in the 1976 MDA, the statute whose meaning is before this Court. These include the power to issue cease-and-desist orders barring the distribution and use of dangerous devices, 21 U.S.C. § 360h(e)(1)(A), to order the recall of devices, *id.* § 360h(e), and to impose civil penalties for violations of the FDCA with respect to devices, *id.* § 333(g)(1)(A). These provisions enhancing FDA authority were actually added fourteen years after passage of the MDA when Congress enacted the 1990 Safe Medical Devices Act, P.L. No. 101-629, 104 Stat. 4511 (codified in various sections of 21 & 42 U.S.C.) (the 1990 Act). The 1990 Act also expanded the FDA's duty to order manufacturers to notify doctors and hospitals regarding dangerous devices (another authority Medtronic cites), 21 U.S.C. § 360h(e)(1)(B), and granted the FDA new authority to issue subpoenas for witnesses and evidence in investigations regarding the assessment of civil penalties, *id.* § 333(g)(2)(A), and to require post-market surveillance of devices when necessary to protect the public, *id.* § 360*l*

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[6] To justify such a remedy the FDA was required to show not only that the device posed "an unreasonable risk of substantial harm to the public," but also that there were reasonable grounds to believe that the device was not properly designed and built in light of the state of the art at the time of such design and manufacture. This "state of the art" requirement created problems of proof for the FDA, and it kept the Agency from acting with respect to even concededly defective medical devices. *See* Staff of Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn"; Shiley Inc.'s Breach of the Honor System and FDA's Failure in Medical Device Regulation*, Comm. Print 101-R, 101st Cong., 2d Sess. 5 (1990). The weak authority provided by this MDA provision not only prevented FDA formal action; it also weakened the Agency's hand in negotiating voluntary recalls by manufacturers. Adler, 43 Food Drug Cosm.L. J. at 530.

The strengthening provisions in the 1990 Act underscore the 1976 law's total inadequacy as a replacement for the tort system in protecting the public against hazardous devices: to start with, no civil penalties, no subpoena power, no effective post-market monitoring, and no effective recall power. Otherwise, the 1990 strengthening provisions are of little relevance to the Court's central inquiry: What does the 1976 MDA's preemption provision mean? Because the 94th Congress gave the FDA relatively weak authority to regulate medical devices, *even in tandem with state tort law*, as the 101st Congress apparently concluded, this Court should not lightly infer that the 94th Congress meant to preempt all tort remedies.

In any case, even after the 1990 amendments, Congress could not have considered the FDA system an adequate substitute for the tort system. The 1990 amendments have done little if anything thus far to steer new device clearances away from the hands-off 510(k) process. In addition, the civil fines that the FDA is now permitted to impose (a maximum of $15,000 for each violation and $1 million for all violations in a single proceeding) are small in comparison to potential damages resulting from dangerous devices affecting thousands of people. Such fines may well be insufficient to deter violations where lucrative opportunities arise in the medical device field. [7]

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[7] Neither the 1990 Act nor its legislative history indicate that the 101st Congress believed that federal law preempted state tort claims concerning medical devices. Indeed, at the time the Safe Medical Devices Act was enacted in November 1990, most, if not all, courts that had considered the issue of MDA preemption of tort law found preemption, if at all, only with respect to claims regarding the adequacy of warnings in cases involving tampons whose packages included specific warning language mandated by the FDA. *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989). It was not until 1992 that any appellate court found that the MDA had more general preemptive effect. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992).

3. Lack of Damage Remedies

Finally, nothing in the 1976 Act or elsewhere in the federal regulatory scheme, even after the 1990 amendments, permits victims of defective medical devices, or their survivors, to obtain compensation for personal injuries. The MDA does not authorize individual damage suits, and the courts have not implied a private right of action. *See, e.g., Bailey v. Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995).[8]

This Court faced a similar situation in *Silkwood v. Kerr-McGee Corp*. There the survivors of Karen Silkwood sought damages in tort against the operator of a nuclear power plant for Silkwood's contamination by plutonium. Although this Court acknowledged that Congress had intended to occupy the "entire field of nuclear safety concerns, except the limited powers expressly ceded to the states," 464 U.S. at 251 (citing *Pacific Gas & Elec. Co. v. Energy Resources Conserv. & Dev. Comm'n*, 461 U.S. 190, 212 (1983)), it ruled that the Silkwood family's tort action was not preempted. What this Court said in that case is apt here: "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Id.*

It is particularly difficult to believe here that Congress would have taken the radical step of preempting tort remedies — granting manufacturers immunity — with respect to one category of products, medical devices, without providing any explanation whatsoever as to why medical devices in particular were entitled to such exemption. The public, organizations concerned with public health and safety, and, indeed, manufacturers, would have wanted to know the basis on which Congress was exempting

[8] The weak repair, replacement and refund provision in the 1976 Act, *see* fn. 6, *supra*, had it ever been used, apparently would have allowed victims to recover only the purchase price of a defective device. Thus, under this provision, alleged victims of the Dalkon shield, including at least 18 women who died and thousands who suffered infections, became infertile, or bore severely handicapped children, *see* Washington Post, Apr. 7, 1985, at A1; N.Y. Times, Aug. 1, 1984, at D1, col. 3, would have been entitled to receive back from the A.H. Robins Company only what they paid for the Dalkon Shield — less than $100.

medical devices from product liability rules without doing the same for other products, such as foods, drugs and cosmetics, which had long been regulated under the same statute and by the same federal regulatory agency.

The limited preemption of tort remedies recognized by this Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), does not call into question this Court's conclusion in *Silkwood* that it is inappropriate to infer, without explicit evidence, a congressional intent to eliminate all remedies for persons claiming injury from some category of harm. This Court's decision in *Cipollone* did not provide cigarette makers with blanket immunity from most or all theories of tort liability — as the power plant operator urged in *Silkwood* and Medtronic urges here — or even from any particular type of tort claim. Instead, Justice Stevens' plurality opinion carefully interpreted the preemption clause of the Public Health Cigarette Smoking Act of 1969 to bar only certain aspects of some of the tort claims brought by the son of a deceased smoker against tobacco companies.

The *Cipollone* plurality reached a plausible result: Congress had mandated precise warnings about the health effects of smoking on cigarette packages and advertising. The applicable preemption clause, barring any further state "requirement or prohibition based on smoking and health ... with respect to the advertising or promotion of any cigarettes," meant that cigarette makers could not be expected to say more about the health effects of smoking in those particular forums. The states were thus prohibited, through tort law or otherwise, from penalizing cigarette makers for failing to provide additional warnings in those places. Thus the plurality recognized that Congress meant to establish uniform package and advertisement warnings. After *Cipollone*, victims of smoking remain free to seek damages against tobacco makers under all state tort theories. They are barred only from basing a claim of failure to warn or fraudulent representation, in whole or in part, on a manufacturer's failure to place additional warnings on cigarette packages or advertisements. Plaintiffs may continue to argue that manufacturers should have provided additional health warnings in other forums or that manufacturers made false statements about the health effects of their products, either on packages or advertisements or elsewhere. *See* 505 U.S. at 524-30 (plurality opinion).

C. Inadequate Funding of the FDA from the 94th Congress to the Present Has Further Weakened the Capacity of the Agency to Ensure Health and Safety

The Lohrs' position — that the provisions of the MDA cannot be read to direct that the FDA regulatory system replace the tort system — is bolstered by the fact that the 94th Congress and its successors have never provided the agency with sufficient funds to meet even the limited mandate of the MDA.

It is widely accepted that the FDA has lacked and still lacks the financial resources to evaluate carefully and efficiently the products of the some 7000 medical device makers, particularly Class III devices. See Adler, 43 Food Drug Cosm. L.J. at 530; Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *Less Than the Sum of Its Parts; Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health*, Committee Print 103-N, 103d Cong., 1st Sess. 9, 14 (1993) ("Less Than the Sum"); N.Y. Times, Aug. 8, 1982, sec. 4, at 7, col. 1 ("[FDA Bureau of Medical Devices] personnel say they are overwhelmed by the number and kinds of medical devices and products they must regulate. A staff of 707 and a $28 million budget, they say, pale when faced with some 1,800 [types of] medical devices now on the market that require classification and another 43,000 products that must be registered").[9] If Congress had genuinely intended the MDA to provide the only legal protections against dangerous medical devices, Members in favor of strong health and safety protection, not to mention consumer organizations, would have treated Congress's failure to fund the Act's enforcement as a very grave matter.

Congress's failure to provide sufficient resources to cope with the rapid development of medical devices has kept the FDA where

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[9] In recognition of the fact that annual appropriations have been insufficient even to fund the limited review provided by the MDA, FDA Commissioner Kessler is now seeking authority from Congress to require medical device manufacturers to pay fees for pre-market reviews under both PMA and 510(k) procedures. Testimony of FDA Commissioner Kessler, Apr. 6, 1995.

the 1976 Act permits the agency to remain: in the thrall of the relatively quick, inexpensive and industry-preferred 510(k) procedure. Because of the abbreviated nature of the 510(k) process, "the agency's main source of information to assess the safety and effectiveness of devices before they reach users is the [good manufacturing practices] inspection process." U.S. General Accounting Office, *Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority* 2 (GAO/PEMD-92-10 Feb. 1992). But FDA efforts in this area, too, have been weakened by funding shortfalls: When a 1992 General Accounting Office study found that the agency had failed to inspect many device makers for substantial periods, *id.*, the FDA responded that it was hampered by limited resources. *Id. at* 92-96.

To conclude that the 94th Congress meant to take the radical step of preempting state tort law with respect to medical devices, this Court would have to find that although Congress said one thing — it wanted to protect the public against harmful medical devices — it in fact intended another — to eliminate tort liability for medical devices and replace that system with limited federal enforcement authority and funding insufficient to carry out even that authority. Of course, it is possible, though there is not a single piece of evidence, that some Members of Congress had, but concealed, such a cynical motivation as they crafted the 1976 legislation. But such speculation is no substitute for the clear evidence that this Court has always required in order to find preemption of matters historically governed by the states.[10]

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[10] Representative Henry Waxman, a member of the Subcommittee on Health and the Environment of the House Commerce Committee at the time of passage of the 1976 Act (and later chairman of the subcommittee) and a supporter of the Act, for one, did not detect such cynicism among his colleagues:

> I can assure you that it was never my intent that the Medical Device Amendments preempt state product liability laws in any way. Nor am I aware of any person who was a Member of Congress in 1976 who intended such preemption. Certainly, preemption of State product liability laws would have been a significant issue, which would have engendered significant opposition if the Members had thought the law could have

III. THE MANY CASES OF SEVERE INJURY CAUSED BY MEDICAL DEVICES SINCE 1976 SHOW THE LIMITED NATURE OF THE FDA'S AUTHORITY AND UNDERSCORE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE TORT SUITS

A. The Tort System Has Functioned As Congress Envisioned When It Passed the MDA: As a Necessary Complement To Federal Authority

That Congress never meant the FDA's limited regulatory authority to become the sole guardian of public safety with respect to medical devices is supported by evidence from the real world. There have been many cases in addition to the Bard catheter case discussed in part II.B.1, *supra*, in which medical devices put on the market with the FDA's blessing — some through the 510(k) process, others through the pre-market approval process — caused severe harm to individuals. In most cases, the public was protected only through the tort system.

For 20 years, the tort system has worked in tandem with the limited system of regulation established by the MDA to improve public health and safety, punish wrongdoing, and reward responsible business conduct.[11] Tort actions have provided the only means to compensate victims for their personal injuries. Moreover, for 15 years after Congress enacted the MDA, tort suits also provided the only means to make irresponsible manufacturers pay any civil financial penalties for misconduct. Thus, tort law has been the primary mechanism for deterring the manufacture and

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been interpreted in this way.
Letter from Representative Henry A. Waxman to Robert Steinberg (Aug. 10, 1993), reproduced in *Talbott v. C.R. Bard, Inc.*, No. 95-1321, Petition for Writ of Certiorari at Appendix M, 94a-95a.

[11] MDA procedures can assist responsible companies in avoiding potential liability. Indeed, *amici* do not contend that juries cannot or should not weigh evidence of compliance with FDA requirements and procedures in considering whether a company acted reasonably. This case is about whether victims of dangerous medical devices will have the opportunity to present their claims at all.

sale of dangerous medical devices. And information obtained and brought to public attention through tort litigation has been crucial in informing the marketplace and spurring the FDA to take necessary action.

As the following cases show, and as Congress knew in 1976, the powers conferred under the MDA are insufficient to permit the FDA to do the job alone.

B. The Bjork-Shiley Heart Valve

Surgeons implant mechanical heart valves to replace patients' diseased or deformed valves. The FDA approved the Bjork-Shiley convexo-concave heart valve through the MDA's pre-market approval process in April 1979. During clinical trials, one of the valves had fractured. The manufacturer, Shiley, Inc., called the incident an anomaly, although it knew of other such fractures. A 1990 report by FDA staff members found that Shiley gained FDA approval for the device by withholding material information regarding the defect. It also concluded that Shiley engaged in repeated efforts to obstruct FDA investigation and keep the device on the market. Johnson, *et al.*, Report of the Shiley Task Group (Dec. 1990); *see* Less Than the Sum, *supra*, at 21.

In January 1984, despite confirmation of 73 fractures causing 58 deaths, the FDA decided not to seek a recall of the valves; instead the agency asked Shiley for more data. After receiving limited data, the FDA decided, in July 1984, to take no action. *Id.* at 28. FDA officials, according to a congressional staff report, explained that the agency had not invoked its recall (repair/replace) authority under the 1976 Act because that authority was "so lengthy and difficult to sustain in court that it has never been used." *Id.* at 5. The authorities provided by the MDA not only failed to keep the defective valves of the market; they also prevented the FDA from acting even in the face of clear evidence of injury.[12]

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[12] Bjork-Shiley heart valve recipients live with fear. A recent article described the ordeal of Elaine Levenson, the founder of *amicus* VALV:

> Elaine Levenson lies in bed each night listening to the clicking of the artificial valve implanted in her heart. As long

About 40,000 people in the United States received the valves before Shiley removed them from the market in 1986. By 1990, at least 389 valves had fractured, resulting in 248 deaths. Staff of Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn"; Shiley Inc.'s Breach of the Honor System and FDA's Failure in Medical Device Regulation*, Comm. Print 101-R, 101st Cong., 2d Sess. 2 (1990).

The tort system offered the only effective response. Litigation, including a 1992 class action settlement against Shiley and its corporate parent, Pfizer, provided some financial redress for the surviving valve recipients. *See Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992).[13]

> as she hears that sound, she knows her Bjork-Shiley heart valve hasn't malfunctioned. Levenson has lived for five years now with the knowledge that the implant could fracture at any moment.....
>
> Fear has changed every aspect of Levenson's life. She used to walk six miles a day and play tennis, but she has stopped exercising because she's afraid it might strain her implant. She doesn't like to stay alone with her grandchildren, because they wouldn't know what to do if her device broke.... Her cardiologist says she will know instantly if the valve malfunctions. "It will be the mother of all pain," he has told her....
>
> Several surgeons have advised Levenson against removing her ... valve on the grounds that she might die during open-heart surgery.... [A]t 57, she feels trapped. "I'd rather take the risk of lying on an operating table now, because at least I'd have a chance," says Levenson. "The hardest thing is being so scared all the time. It's very stressful living with a time bomb inside you and not knowing when it's going to blow."

Green, *Dangerous Devices; Artificial Implants*, American Health, Jan. 1995, at 68.

[13] More recently, Shiley has contended that the MDA preempts tort claims. *See, e.g., Michael v. Shiley*, 46 F.3d 1316 (3rd Cir. 1995) (finding some, but not all, claims preempted), *cert. denied*, 116 S.Ct. 67 (1995).

C. The Vitek Jaw Implant

Vitek, Inc., developed a jaw implant made of Teflon for persons suffering from a painful condition called temporomandibular joint disorder. Vitek's implants entered the market through the MDA's 510(k) substantial equivalence process; there was no FDA review of safety or effectiveness. Between 1983 and 1990, more than 26,000 people received the implants. What they did not know was that Vitek had never tested the product in animals or humans before the implants were marketed. Experience showed that the devices tended to fragment, leading to deterioration of the skull and debilitating pain. In 1988, Vitek, under the pressure of hundreds of lawsuits filed by patients (total claimants eventually reached 3,000), stopped selling its defective implants. Only after these developments did the FDA, in 1990, issue a safety alert. *See* Connelly, *Jaw Implant Suit Takes the Fast Track*, Texas Lawyer, July 17, 1995, at 6; Boston Globe, June 5, 1992, at 11; N.Y. Times, June 5, 1992, at A14, col. 2.

D. Playtex Super-Absorbent Tampons

Betty O'Gilvie, a Kansas woman, died in 1983 from toxic shock syndrome after using Playtex super-absorbent tampons. The MDA had not required Playtex to demonstrate the safety or effectiveness of these tampons: Implementing the MDA's provisions, the FDA had classified tampons as Class II devices. As such, tampons were subject only to performance standards — standards the agency never issued.

As the Tenth Circuit Court of Appeals later found, there was "abundant evidence that Playtex deliberately disregarded studies and medical evidence linking high-absorbency tampon fibers with increased risk of toxic shock at a time when other manufacturers were responding to this information by modifying or withdrawing their high-absorbency products." *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438, 1446 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988). The court also noted "evidence that Playtex deliberately sought to profit from this situation by advertising the effectiveness of its high absorbency tampons ...." *Id.* In 1985, a federal jury awarded O'Gilvie's family $1.5 million in compensatory damages and $10 million in punitive damages.

Playtex promptly removed the tampons from the market, improved its warnings on other products about toxic shock syndrome, and began an effort to increase public awareness of the problem. The trial judge remarked that the suit had "literally changed an industry." Bates, *TSS Award Slashed After Playtex Stops Selling Tampon*, The National Law Journal, June 10, 1985, at 10.

E. The Airco Ventilator

Airco, Inc., sold a ventilator that assisted patient breathing during surgery. The family of Georgia Huchingson, an Arkansas woman, sued the company after she suffered brain and lung damage as a result of being connected to the device during a May 1980 operation; she died in January 1982. A jury concluded that the ventilator was defectively designed because it included a switch that made it easy for operators to inadvertently misuse the machine, resulting in oxygen deprivation to the patient. The Arkansas Supreme Court, upholding an award of punitive damages against Airco (the first time that court had approved a punitive damages award in a product liability suit), ruled that Airco "knew from the outset, by its very own testing, that an unnecessary component of the product was so deadly that it should never have been made available to the public." *Airco, Inc. v. Simmons First National Bank*, 638 S.W.2d 660 (Ark. 1982). As a result of the family's victory in court, Airco voluntarily issued a medical device alert through the FDA, warning physicians and hospitals of the potential danger.

F. Orcolon Eye Gel

Orcolon eye gel, manufactured by Optical Radiation Corporation (ORC), was designed to steady the eyeball during cataract surgery. The gel was supposed to dissipate immediately after surgery. In clinical trials of the product, however, it failed to do so and created dangerously high eye pressure, requiring at least two patients to undergo emergency surgery to prevent blindness. Nevertheless, the agency approved Orcolon through the PMA process in March 1991. Soon after, doctors began reporting cases of increased pressure and loss of sight. By the time ORC, at FDA's request, withdrew the gel in October 1991, the product

had caused total or partial blindness in at least 100 people. By March 1992, there were over 270 reports of adverse reactions. Less Than the Sum, *supra*, at 30; Green, *Dangerous Devices; Artificial Implants*, American Health, Jan. 1995, at 68. Once again, PMA procedures were simply inadequate to prevent or redress harm.

G. Silicone Breast Implants

Since the 1960's, an estimated one million women in the United States have received gel-filled silicone breast implants, some for cosmetic enhancement and others for reconstruction following mastectomy. There has been enormous controversy over claims that the implants cause connective tissue disorders. Major ongoing studies, including one at the National Institutes of Health, may help resolve the dispute.[14] It is already clear, however, that the implants tend to rupture, causing silicone gel to leak into the bodies of recipients. Citing published studies, FDA Commissioner David A. Kessler has stated that the "rupture and bleed rate is somewhere between 5 and 71 percent." *Nightline* (ABC television broadcast, Aug. 17, 1995). Leakage can cause pain and swelling. Id.

Breast implants were grandfathered when the MDA was enacted in 1976, and models developed thereafter were marketed pursuant to section 510(k). The FDA took no action until 1988, when it classified silicone implants as Class III devices. The agency called for pre-market approval applications in 1991. *See* Less Than the Sum, *supra*, at 25; Testimony of FDA Commissioner David A. Kessler before the House Subcomm. on Human Resources and Intergovernmental Relations, Comm. on Government Reform and Oversight, Aug. 1, 1995.

By then, lawsuits brought by implant recipients, and not FDA review, had exposed deficiencies in the devices. In particular,

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[14] The largest completed study to date, partly funded by implant makers and directed by a Harvard Medical School epidemiologist, found that women with breast implants were 24 percent more likely to report connective tissue diseases than women without implants. Washington Post, Feb. 28, 1996, at A13.

discovery in tort litigation had, by the early 1980's, unearthed internal corporate records showing that officials at Dow Corning, the dominant maker of the implants, had done insufficient testing to ensure the long-term safety of the devices and had long been aware that the implants tended to leak and that silicone posed risks for the human body. *See* Frankel, *From Pioneers to Profits*, The American Lawyer, June 1992, at 82; Washington Post, Mar. 3, 1992, at Z10. Only after litigation opened the manufacturers' files did the FDA, on January 6, 1992, request a voluntary moratorium on the use of silicone gel implants pending further review. The agency subsequently restricted use of the implants to patients participating in clinical investigations and research studies.

H. Pedicle Screws

In the early 1980's, some surgeons began using bone screws in spinal fusion surgery. Implanted in narrow archways in the spine called pedicles, the devices attach metal plates to patients' vertebrae. The FDA allowed marketing of the screws, through the 510(k) process, for use in arm and leg bones. But the agency, concerned about the proximity of the screws to the spinal canal and nerve roots, approved only clinical testing of the pedicle procedure.

Nevertheless, and unlawfully, manufacturers began to promote the screws for general use in the spine. Since the mid-1980's, the screws have been implanted in the spines of some 300,000 people. Patients have suffered a range of adverse results, including intense chronic pain, loss of sensation in the legs, and sexual dysfunction.

Instead of seeking to punish the manufacturers, the FDA is now proposing that controls on the screws be loosened by downgrading them from Class III to Class II. The agency has also granted 510(k) marketing clearance for some pedicle screws.

Tort litigation, meanwhile, has unearthed vital information, some that the FDA had never obtained (and some that the agency had obtained but never acted on). A lawsuit involving over 3,000 claimants, *In Re: Orthopedic Bone Screw Product Liability Litigation*, M.D.L. Docket No. 1014 (E.D.Pa.), has revealed that companies falsified data and marketed the screws for use in the pedicles without any animal or human testing; that surgeons

promoted the use of the screws while receiving stock options from their manufacturers; that the FDA relied on studies prepared by some of those same surgeons; and that a consulting firm had, on the advice of its counsel, systematically implemented what the trial judge has termed a document "destruction policy" with respect to records associated with one of the FDA studies. *See* MacLachan, *Bone Screw Suit Places FDA in 4-Way Squeeze*, The National Law Journal, Jan. 8, 1996, at A1. Once again, it is the tort system, and not MDA procedures, that is bringing to public attention information crucial to allowing an informed decision on medical devices. But manufacturers are seeking to halt the litigation and further disclosures by arguing that the MDA preempts the plaintiffs' claims. *Id.*[15]

IV. A FINDING OF PREEMPTION HERE WOULD OPEN THE FLOODGATES FOR DEMANDS FOR JUDICIALLY-CREATED TORT IMMUNITY

As the Lohrs have persuasively argued, the fact that this Court in *Cipollone* concluded that the phrase "requirement or prohibition," in the context of the Public Health Cigarette Smoking Act of 1969 encompassed common law tort actions does not compel the conclusion that the word "requirement" in section 360k(a) of the MDA does the same. However, if this Court does find preemption in this case, it may be difficult for lower courts across the country to avoid the conclusion that other federal

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[15] The Bard catheter, Bjork-Shiley valve, and pedicle screw cases are not the only major ones in which courts, citing federal preemption, are now dismissing tort claims alleging injuries from medical devices. Other cases involve injuries caused, for example, by allegedly defective penile implants (510(k) devices), *see Duvall v. Bristol-Myers-Squibb Co.*, 65 F. 3d 392 (4th Cir. 1995), *petition for cert. filed*, Dec. 22, 1995, No. 95-1010; *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *petition for cert. filed*, Dec. 26, 1995, No. 95-1034; and injectable collagen (PMA device), which has been used to treat wrinkles and acne but has been linked to autoimmune diseases, *see King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S.Ct. 86 (1993).

statutes with preemption provisions that include the word "requirement," regardless of the context in which the word is used, preempt a range of other tort claims. Indeed, preemption provisions in the Consumer Product Safety Act ("CPSA") and the Federal Hazardous Substances Act ("FHSA") are quite similar to that in the MDA.[16] That courts may begin to find that those

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[16] The MDA's main preemption provision, 21 U.S.C. § 360k (a), provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

A preemption provision in the FHSA, 15 U.S.C. § 1261 note, as amended, relating to dangerous toys and household products, states in relevant part:

> [I]f under the regulations of the Commission ... a requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.

The preemption provision in the CPSA, 15 U.S.C. § 2075, as amended, states in relevant part:

> Whenever a consumer product safety standard under this Chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

statutes, too, preempt common law is not idle speculation. *See, e.g., Moe v. MTD Products, Inc.*, 73 F.3d 179 (8th Cir. 1995) (CPSA preempts claims for strict liability, negligence, and breach of implied warranties arising when 17-year-old boy's fingers amputated by lawnmower). Thus, a decision by this Court in favor of Medtronic could indeed effect extraordinarily significant nationwide tort "reform," eliminating consumer remedies with respect to thousands of consumer products, without a single purposeful legislative vote.

CONCLUSION

For the foregoing reasons, *amici* urge the Court to affirm the Eleventh Circuit insofar as that court held that federal law did not preempt the Lohrs' common law claims and reverse the Eleventh Circuit insofar as it found federal preemption.

Respectfully submitted,

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March 13, 1996

The CPSA and FHSA, like the MDA, permit States and their subdivisions to petition federal regulators for permission to enact more stringent safety requirements — a procedure that has no relevance to common law tort rules. *See* Brief for Cross-Petitioners Lora Lohr and Michael Lohr at 23-27.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.
Petitioner/Cross-Respondent,
v.
LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF THE HEALTH INDUSTRY MANUFACTURERS ASSOCIATION AND MEDMARC INSURANCE COMPANY AS *AMICI CURIAE* IN SUPPORT OF PETITIONER/CROSS-RESPONDENT, MEDTRONIC, INC.

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69 pp

QUESTION PRESENTED

Whether the Food and Drug Administration's comprehensive regulation of medical devices establishes requirements that preempt state-law product liability and related claims pursuant to section 521 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

TABLE OF AUTHORITIES vi

INTEREST OF THE *AMICI CURIAE* 1

SUMMARY OF ARGUMENT 1

ARGUMENT 3

I. THE FDA'S COMPREHENSIVE REGULATION OF DEVICES ESTABLISHES REQUIREMENTS THAT EXPRESSLY PREEMPT STATE PRODUCT LIABILITY AND RELATED CLAIMS 3

A. Congress And The FDA Have Established A Comprehensive Scheme For Regulating The Safety And Effectiveness Of Medical Devices 3

1. The FDA implements a classification scheme to ensure that medical devices receive the appropriate level of safety and effectiveness review 4

Page

2. The FDA authorizes the marketing of most medical devices through the section 510(k) premarket notification and authorization process 6

3. The FDA requires certain Class III devices to obtain marketing authority through the premarket approval process 6

4. The FDA may take regulatory action if new safety or effectiveness concerns are raised 8

5. The FD&C Act and FDA regulations impose safety and effectiveness requirements on all medical devices 8

a. GMP regulations 8

b. Warning requirements 9

B. The Section 510(k) Premarket Notification And Authorization Process Imposes Preemptive Requirements On Medical Devices 10

1. A determination of substantial equivalence involves an evaluation of the safety and effectiveness of the device 12

Page

2. The level of scrutiny the FDA imposes on a medical device through the section 510(k) process is based on a reasoned determination of the level of risk posed by the particular device 16

C. The Labeling, Manufacture, And Design Of Medical Devices Are Regulated By The FDA Through The Section 510(k) Process And GMP Regulations 19

1. Labeling 19

2. Design and manufacture 20

II. PERMITTING STATE PRODUCT LIABILITY AND RELATED CLAIMS TO PROCEED AGAINST MEDICAL DEVICE MANUFACTURERS WOULD STIFLE INNOVATION AND IMPEDE THE AVAILABILITY OF IMPORTANT MEDICAL TECHNOLOGIES 22

A. The Imposition Of Awards Against Medical Device Manufacturers Under State Law Would Impede The Development Of Important Medical Technologies 24

B. The Imposition Of State Awards Would Threaten The Availability Of Critical Medical Technologies 25

Page

1. Useful products have been withdrawn because of liability concerns 25

2. Liability awards would impose social costs, with no countervailing public benefits 28

CONCLUSION 30

TABLE OF AUTHORITIES

Page(s)

REGULATIONS AND RULES

21 C.F.R. § 801.109 10
21 C.F.R. § 801.109(c) 10
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Page(s)

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FD&C Act § 502(f)(2), 21 U.S.C. § 352(f)(2) 8, 9
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FD&C Act § 510, 21 U.S.C. § 360 8
FD&C Act § 510(k), 21 U.S.C. § 360(k). 6, 10, 11, 17, 19
FD&C Act § 513, 21 U.S.C. § 360c 4
FD&C Act § 513(a)(1)(A), 21 U.S.C. § 360c(a)(1)(A) . . 4
FD&C Act § 513(a)(1)(B), 21 U.S.C. § 360c(a)(1)(B) . . 5
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FD&C Act § 513(e), 21 U.S.C. § 360c(e) 8
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FD&C Act § 513(i), 21 U.S.C. § 360c(i) 12
FD&C Act § 513(i)(1)(A), 21 U.S.C. § 360c(i)(1)(A) . 12
FD&C Act § 514(b), 21 U.S.C. § 360d(b) 4
FD&C Act § 515(b), 21 U.S.C. § 360e(b) 4, 11
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Page(s)

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FD&C Act § 515(e), 21 U.S.C. § 360e(e) 8
FD&C Act § 518, 21 U.S.C. § 360h 8
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FD&C Act § 520(g), 21 U.S.C. § 360j(g) 7
FD&C Act § 520(l), 21 U.S.C. § 360j(l) 4
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INTEREST OF THE *AMICI CURIAE*

The Health Industry Manufacturers Association (HIMA) is the principal trade association of the medical technology industry. Founded in 1974, HIMA represents more than 700 manufacturers of medical devices, diagnostic products, and health information systems, along with component manufacturers and manufacturing services suppliers. HIMA's members manufacture more than 90 percent of the nearly $40 billion of health care technology products purchased annually in the United States.

MEDMARC Insurance Company, Inc. (MEDMARC) is a specialty insurer which provides product liability coverage for medical device manufacturers. Owned and controlled by its members, MEDMARC was founded in 1979 in response to volatile conditions in the commercial insurance market for product liability insurance. MEDMARC's membership includes approximately 550 manufacturers and distributors of medical devices and diagnostic products.

The present case raises an issue of fundamental and overriding importance to the medical device industry. *Amici* are concerned that the imposition of inconsistent state requirements on medical device manufacturers through product liability awards will stifle innovation and interfere with the availability of life-saving technologies.[1/]

SUMMARY OF ARGUMENT

Congress preempted additional or inconsistent state requirements to protect a uniform national market for medical devices. In enacting the express preemption provision of the Medical Device Amendments, Congress carefully weighed the need for innovation and progress in the medical device field, which is fostered by a uniform national regulatory system,

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[1/] Pursuant to Rule 37 of the Rules of this Court, the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of the Court.

against the interests of the states in imposing their own inconsistent or additional requirements. Congress struck the balance by placing the regulation of the safety and effectiveness of medical devices solely in the hands of the Food and Drug Administration (FDA), thus ensuring that no single state can raise its individual interests above the congressional policy favoring development and regulation of medical devices under a single national authority.

Pursuant to its statutory mandate, the FDA has established a comprehensive system to assure the safety and effectiveness of medical devices. The FDA utilizes a variety of regulatory controls to ensure that device manufacturers are subject to appropriate safety and effectiveness requirements for their products. Among other things, the FDA conducts premarket review and approval of product submissions, imposes specific manufacturing and labeling requirements, and implements a classification scheme and product review policy to ensure that medical devices receive the appropriate level of safety and effectiveness review. As Congress expressly decreed, these and other requirements imposed on medical device manufacturers under the FDA's complex regulatory framework preempt different or additional state requirements, including those imposed through product liability and related claims.

Congress recognized that state product liability exposure relating to the safety or effectiveness of medical devices would threaten innovation and impede the availability of important medical technologies. Indeed, liability concerns already have driven valuable products off the market and have hindered critical research deemed to present too high a liability risk. To prevent these detrimental influences from chilling the advancement of medical device technology, Congress entrusted the safety and effectiveness of devices exclusively to the FDA's expert authority.

ARGUMENT

I. THE FDA'S COMPREHENSIVE REGULATION OF DEVICES ESTABLISHES REQUIREMENTS THAT EXPRESSLY PREEMPT STATE PRODUCT LIABILITY AND RELATED CLAIMS.

In 1976, Congress enacted the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The new legislation greatly enhanced the FDA's authority to ensure that medical devices are safe and effective for their intended uses. To ensure that the FDA's expert regulatory control would not be undermined by divergent state requirements, Congress included an express preemption provision in the legislation, providing that a state requirement is preempted if it is "different from, or in addition to" any applicable federal requirement relating to device safety or effectiveness.[2/] Pursuant to its congressional mandate, the FDA has developed a complex regulatory framework for assuring the safety and effectiveness of medical devices. An award of damages to a plaintiff under state law would impose requirements for medical devices that are different from or in addition to those imposed under the FDA's comprehensive regulatory scheme. Therefore, claims against medical device manufacturers premised on state product liability, warranty, or similar laws (whether imposed by statute or by common law) are expressly preempted.

A. Congress And The FDA Have Established A Comprehensive Scheme For Regulating The Safety And Effectiveness Of Medical Devices.

Under the MDA, the FDA comprehensively regulates the safety and effectiveness of medical devices. Through this system, the FDA implements a variety of regulatory controls,

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2/ FD&C Act § 521(a), 21 U.S.C. § 360k(a).

which operate in concert to facilitate the availability of important medical devices while ensuring that products posing unreasonable risks to public health and safety are not released into or are removed from the market. With the assistance of expert advisory panels, the FDA exercises its statutory discretion to tailor the level of regulatory control and review for specific medical devices to fit the particular safety and effectiveness concerns they raise. Through the classification scheme, premarket approval process, "510(k)" premarket notification and authorization process, performance standards, and general controls, the FDA assures the safety and effectiveness of medical devices.

1. **The FDA implements a classification scheme to ensure that medical devices receive the appropriate level of safety and effectiveness review.**

As required by Congress, the FDA imposes requirements based on the level of regulation the agency deems necessary to assure the safety and effectiveness of particular devices. The FDA implements a statutory classification scheme to determine the level of scrutiny appropriate for different types of medical devices.[3/] Devices are classified in one of three categories — Class I, Class II, or Class III. Devices classified in Class I are deemed to pose the lowest risk to human health and are subject to general controls under the FD&C Act.[4/] In addition, unless exempted by the FDA, Class I devices can be marketed only through the section 510(k) premarket notification and authorization process, described below.

[3/] *See* FD&C Act §§ 513, 514(b), 515(b), and 520(l), 21 U.S.C. §§ 360c, 360d(b), 360e(b), and 360j(l); 21 C.F.R. Part 860.

[4/] 21 C.F.R. § 860.3(c)(1); FD&C Act § 513(a)(1)(A), 21 U.S.C. § 360c(a)(1)(A). General controls are discussed below in part I.A.5.

The FDA places a medical device in Class II if it determines that the device requires additional regulatory controls to assure its safety and effectiveness.[5/] Class II devices are subject to general controls and the section 510(k) requirements. In addition, they may be subject to "special controls," such as particularized performance standards, postmarket surveillance, patient registries, and other appropriate actions the FDA deems necessary to assure safety and effectiveness.[6/] For example, the FDA imposes specific labeling requirements on manufacturers of tampons regarding the risk of toxic shock syndrome to assure that these devices are used in a safe and effective manner.

The FDA will classify a medical device in Class III if the device is "life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury."[7/] A Class III device cannot be marketed except pursuant to an affirmative grant of authority by the FDA, which imposes precise conditions governing the device's design, manufacture and labeling. The manufacturer of a Class III medical device may obtain the required marketing authority from the FDA via one of two premarket review processes — the section 515 premarket approval process or, for devices "substantially equivalent" to pre-MDA devices and not required to go through the section 515 procedure, the section 510(k) premarket notification and authorization process.

[5/] 21 C.F.R. § 860.3(c)(2); FD&C Act § 513(a)(1)(B), 21 U.S.C. § 360c(a)(1)(B).

[6/] 21 C.F.R. § 860.3(c)(2).

[7/] 21 C.F.R. § 860.3(c)(3); FD&C Act § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C).

2. The FDA authorizes the marketing of most medical devices through the section 510(k) premarket notification and authorization process.

Like the pacemaker lead at issue in the instant case, most medical devices are marketed through the premarket notification process under section 510(k) of the FD&C Act.[8/] A medical device may be marketed pursuant to a premarket notification, or "510(k)", if the device is "substantially equivalent" to a predicate device (*i.e.*, a device marketed before enactment of the MDA on May 28, 1976), and if the FDA has not specifically required a premarket approval application (PMA) for the device. Before granting marketing authority, the FDA must determine that the device is substantially equivalent in safety and effectiveness to the predicate device. The FDA's implementation of the section 510(k) process is discussed in more detail in section I.B. below.

3. The FDA requires certain Class III devices to obtain marketing authority through the premarket approval process.

A significant number of Class III devices are marketed pursuant to the PMA process. A PMA is required to market a Class III medical device if the device is not substantially equivalent to a pre-amendment device or if the FDA specifically requires a PMA for that device. The PMA process subjects Class III devices to comprehensive FDA requirements regulating all aspects of their design, labeling, and manufacture.[9/]

[8/] 21 U.S.C. § 360(k).

[9/] Through the Investigational Device Exemption (IDE) regulations, the FDA also subjects investigational devices involved in clinical trials to a (continued...)

In preparing a PMA, a medical device manufacturer must conduct an exhaustive review and analysis of the device's safety and effectiveness. Among other things, the PMA must include "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective" and "a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device."[10/] The PMA also must include "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device."[11/] Moreover, a GMP inspection of the applicant's manufacturing facilities is conducted by the FDA before the PMA will be approved.[12/]

Because this case involves a device marketed through the section 510(k) process, we will not further discuss the PMA process. The preemptive effect of requirements imposed under the PMA process follows *a fortiori* from the preemptive effect of section 510(k) requirements. In any event, the factors that led the court below to stop short of full preemption have no application to the PMA context.

[9/](...continued)
high level of regulatory oversight and control. *See* FD&C Act § 520(g), 21 U.S.C. § 360j(g); 21 C.F.R. Part 812.

[10/] FD&C Act §§ 515(c)(1)(A), 515(c)(1)(B), 21 U.S.C. §§ 360e(c)(1)(A), 360e(c)(1)(B).

[11/] FD&C Act § 515(c)(1)(C), 21 U.S.C. § 360e(c)(1)(C).

[12/] FDA Compliance Program Guidance Manual, Program 7383.001, Medical Device Premarket Approval and Postmarket Inspections (March 1994).

4. The FDA may take regulatory action if new safety or effectiveness concerns are raised.

Even after the FDA grants marketing authority for a Class III device through the section 510(k) or PMA process, device manufacturers are subject to comprehensive recordkeeping and reporting obligations to ensure that they obtain and report to the FDA the most up-to-date information bearing on safety and effectiveness.[13] The FDA has broad authority to withdraw approval of a PMA and to take enforcement action against devices marketed under section 510(k).[14] In addition, the agency often directs manufacturers to add or modify warnings in light of new information.[15]

5. The FD&C Act and FDA regulations impose safety and effectiveness requirements on all medical devices.

All medical devices are subject to certain "general controls" under the FD&C Act and FDA regulations. Among other things, these general controls include good manufacturing practice (GMP) and warning requirements.

a. *GMP regulations*

The GMP regulations (21 C.F.R. Part 820) impose comprehensive requirements on manufacturers of medical devices, covering "methods used in, and the facilities and

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[13] *See* FD&C Act §§ 510, 519, 21 U.S.C. §§ 360, 360i; 21 C.F.R. §§ 803.24, 803.31, 807.20-807.31.

[14] *See, e.g.*, FD&C Act §§ 302 (injunction proceedings), 303 (penalties), 304 (seizure), 513(e) (classification changes), 515(e) (withdrawal and temporary suspension of approval of application), 518 (notification and other remedies), 21 U.S.C. §§ 332, 333, 334, 360c(e), 360e(e), 360h.

[15] *See* FD&C Act §§ 502(a), 502(f)(2), 502(j), 21 U.S.C. §§ 352(a), 352(f)(2), 352(j).

controls used for, the manufacture, packing, storage, and installation of all finished devices intended for human use."[16] These regulations are "intended to assure that such devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act."[17]

Under the GMP regulations, medical device manufacturers must prepare and implement a quality assurance program "that is appropriate to the specific device manufactured" and in accordance with the GMP requirements.[18] The GMP regulations impose extensive quality, manufacturing, design, label control, and recordkeeping requirements on all medical devices,[19] with particularized provisions applicable to critical devices (*i.e.*, devices that are intended for surgical implant or to support or sustain life and whose failure to perform will likely result in significant injury).[20] Any failure of a device or any of its components to meet specifications after it has been released into the market must be investigated by the manufacturer, and the investigation, along with any conclusions or follow-up, must be documented.[21]

b. *Warning requirements*

There are several statutory provisions bearing on device labeling. These provisions include section 502(f)(2) of the

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[16] 21 C.F.R. § 820.1.

[17] *Id.*

[18] 21 C.F.R. § 820.5.

[19] 21 C.F.R. Part 820.

[20] *See* 21 C.F.R. §§ 820.3(e), 820.3(f), 820.81, 820.101, 820.116, 820.121, 820.151, 820.161, 820.182, 820.185, 820.195.

[21] 21 C.F.R. § 820.162.

FD&C Act,[22] which requires "adequate warnings," section 502(a),[23] which prohibits false or misleading labeling, and section 201(n),[24] which, together with section 502(a), prohibits misleading omissions.

In addition, section 502(f)(1) requires device labeling to bear "adequate directions for use."[25] Prescription medical devices, such as the pacemaker lead at issue in the present case, are exempt from the provision requiring "adequate directions for use," if they comply with the labeling requirements of 21 C.F.R. § 801.109, which include "information for use, including indications, effects, routes, methods, and frequency and duration of administrations, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended."[26] The FDA thus requires that adequate warnings be provided to physicians who, in turn, provide such information to patients as may be necessary in the process of securing informed consent.

B. The Section 510(k) Premarket Notification And Authorization Process Imposes Preemptive Requirements On Medical Devices.

The device at issue in the present case is a Class III prescription medical device cleared for marketing through the section 510(k) process. As explained above, the section 510(k) process permits the marketing of a new medical device

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22/ 21 U.S.C. § 352(f)(2).

23/ 21 U.S.C. § 352(a).

24/ 21 U.S.C. § 321(n).

25/ FD&C Act § 502(f)(1), 21 U.S.C. § 352(f)(1).

26/ 21 C.F.R. § 801.109(c).

that the FDA has determined is substantially equivalent to a predicate device. A section 510(k) submission must contain proposed labeling for the device and must demonstrate that the device is substantially equivalent in intended use and technological characteristics to the predicate device, or that any technological differences from the predicate device do not render the device less safe or effective than the predicate device.[27]

The FDA may request additional information that it deems necessary to make a determination of substantial equivalence.[28] The additional information required by FDA may include clinical data or design information intended to assure the agency of the safety and effectiveness of the device. If the FDA finds the labeling proposed by the applicant inadequate, it may require alternative labeling as a condition for its substantial equivalence determination.[29] Once a device is cleared for marketing pursuant to the section 510(k) process, the FDA retains the power to call for a PMA for the device to impose more stringent requirements.[30]

In 1990, the statutory language governing the section 510(k) process was substantially strengthened under the Safe Medical Devices Act of 1990 (SMDA). The SMDA

27/ FD&C Act § 510(k), 21 U.S.C. § 360(k); 21 C.F.R. § 807.87.

28/ 21 C.F.R. § 807.87(k); *see also* Memorandum from David L. West (Deputy Director, Office of Device Evaluation (ODE)) to ODE Review Staff regarding 510(k) Additional Information Procedures (510(k) Memorandum #K93-1) (July 23, 1993) (hereinafter Additional Information Procedures). To illustrate this point, reprinted in Appendix A are some publicly available letters the FDA has sent to medical device manufacturers requesting additional information necessary for the review of their 510(k) submissions.

29/ *See, e.g.*, Appendix A.

30/ FD&C Act § 515(b), 21 U.S.C. § 360e(b).

"confirms the manner in which the agency has implemented the premarket notification provision of the 1976 device law and gives the [FDA] substantial additional postmarket surveillance and penalty authorities."[31/] The FD&C Act now expressly mandates that all relevant information on the safety and effectiveness of the device be included in the section 510(k) submission.[32/] In addition, the SMDA provides that the FDA must issue a formal order embodying its finding that the device either has the same technological characteristics as the predicate device, or does not raise different questions of safety and effectiveness than the predicate device.[33/]

1. A determination of substantial equivalence involves an evaluation of the safety and effectiveness of the device.

The FDA's practice of evaluating safety and effectiveness information in making substantial equivalence determinations did not originate with the SMDA. The section 510(k) process historically has involved a review of device safety and effectiveness. In the preamble to the final rule implementing provisions of the SMDA, the agency rejected the notion that an evaluation of safety and effectiveness is outside of the scope of a substantial equivalence inquiry, and it emphasized that the evaluation of a device's safety and effectiveness has always been integral to the substantial equivalence determination.[34/] The agency explained:

31/ Advisory Committee on the FDA, Final Report, *Report of the Subcommittee on Devices, Radiological Health and Biomedical Research*, App. C, at 16 (May 1991) (hereinafter *Advisory Committee Report*).

32/ FD&C Act § 513(i), 21 U.S.C. § 360c(i).

33/ FD&C Act § 513(i)(1)(A), 21 U.S.C. § 360c(i)(1)(A).

34/ 59 Fed. Reg. 64287, 64288 (Dec. 14, 1994); *see also* H.R. Rep. No. 808, 101st Cong., 2d Sess. 25 (1990); *Advisory Committee Report, supra*, at 16.

> FDA believes that Congress clearly intended the concept of "substantial equivalence" to include some inquiry into the safety and effectiveness of a new device, and that such inquiries into safety and effectiveness are often inseparable from other bases of determining substantial equivalence.[35/]

The position articulated by the FDA in its final rule is supported by the legislative history. Referencing the provisions of the SMDA authorizing FDA to request clinical data in support of section 510(k) applications, the House Committee on Energy and Commerce stated:

> The reference to clinical data is to be read together with the requirement that devices found substantially equivalent may be used with the same assurance of *safety and effectiveness* as similar devices on the market. The Committee believes that such a finding may well necessitate submission of some *clinical data* and intends this provision to *clarify the statutory basis for requiring such information. Again, the Committee does not intend to change current FDA practice regarding this process.*[36/]

The 1986 FDA guidance document for conducting section 510(k) reviews illustrates the FDA's longstanding practice of requesting performance data to substantiate the safety and effectiveness of medical devices. The guidance document stated:

> The Center [for Devices and Radiological Health] normally will require performance testing data to

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35/ 59 Fed. Reg. at 64288.

36/ H.R. Rep. No. 808, at 25 (emphasis added); *see also* H.R. Rep. No. 853, 94th Cong., 2d Sess. 36 (1976) (indicating that safety and effectiveness is a part of the substantial equivalence determination).

> substantiate equivalence if a new device has an important descriptive difference in comparison to marketed devices within its type, and it is *not* clear from an initial review that the device has an intended use or technological change that makes it [not substantially equivalent]; or, the new device has descriptive characteristics that are too imprecise to guarantee that comparability in performance will be achieved even if the new device is produced as described.[37/]

The guidance document used a pacemaker lead, the type of medical device at issue in the present case, to illustrate the circumstances under which performance data would be required.[38/]

[37/] FDA, Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, at 12 (June 30, 1986) (hereinafter 1986 Guidance). This guidance did not initiate the practice of requiring supporting performance data. Rather, the guidance document "describes practices that have been developed over many years of program operations." Memorandum from Kshitij Mohan (Director, ODE) to ODE Review Staff regarding Premarket Notification Review Program (510(k) Memorandum #86-3) (June 30, 1986).

[38/] The guidance stated:

> The fact that a new pacemaker lead and a marketed pacemaker lead are both in the polyurethane "family" does not ensure that both devices have the same chemical formulations, and *differences in the chemical formulations of polyurethanes could affect safety or effectiveness. Differences in design, extrusion, and assembly of polyurethanes with the same chemical formulation could also affect safety or effectiveness.* Thus, the Center would generally *require performance testing information* to confirm that the new lead is [substantially equivalent] to the predicate lead.

1986 Guidance, *supra*, at 12 (emphasis added).

A 1993 draft guidance document confirms that the FDA's review of safety and effectiveness data is not limited to devices that differ technologically from predicate devices. This draft guidance applies to agency review of section 510(k) submissions for devices "that do not feature new technological characteristics that raise new types of safety and effectiveness issues."[39/] It delineates certain "basic information" that should be included in a section 510(k) submission, because "[t]his information is necessary in the evaluation of the safety and efficacy, and the substantial equivalence of a device."[40/] Among other things, this basic information includes comparative performance evaluations and, if appropriate, clinical performance evaluations and data.[41/] In addition, the section 510(k) submission should identify and demonstrate compliance to applicable voluntary standards, which may impose additional safety and efficacy requirements on the device.[42/]

The FDA has issued several other guidance documents to assist in the preparation and review of section 510(k) submissions. These documents provide supplemental guidance to FDA reviewers and medical device manufacturers regarding the substantive requirements of section 510(k) submissions. The FDA guidance documents broadly applicable to section 510(k) submissions are updated periodically.[43/] In addition

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[39/] FDA, Reviewer Guidance for Premarket Notification Submissions, at 1 (Draft Nov. 1993) (hereinafter 1993 Guidance).

[40/] *Id.* at 3.

[41/] *Id.* at 2-6.

[42/] *Id.* at 7.

[43/] The most recent FDA guidance on preparing 510(k) submissions is dated March 1995. *See* Addendum: How to Submit a Premarket Notification [510(k)], *reprinted in* International Medical Device Regulatory Monitor, App. A (Mar. 1995).

to the general section 510(k) guidance documents, the FDA has issued a number of guidances applicable to specific types of devices.[44/] These guidance documents, issued both before and after enactment of the SMDA, are tailored to the particular devices in question, and illustrate the importance of safety and effectiveness data in section 510(k) submissions.

2. The level of scrutiny the FDA imposes on a medical device through the section 510(k) process is based on a reasoned determination of the level of risk posed by the particular device.

The regulation of medical devices is premised on the FDA's expert authority to determine the appropriate level of regulatory review required to assure the safety and effectiveness of particular medical devices. In implementing the section 510(k) premarket notification and authorization process, the FDA exercises its discretion and expertise to determine the appropriate level of safety and effectiveness information required in a section 510(k) submission and the

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[44/] The FDA has issued guidance documents governing 510(k) submissions for numerous devices, including blood oxygenators (Draft Mar. 1983), magnetic resonance diagnostic devices (Aug. 2, 1988), implantable pacemaker leads (Draft Sept. 1989), picture archiving and communications systems (Feb. 1991), computer controlled medical devices (Aug. 29, 1991), sterilizers intended for use in health care facilities (Mar. 1993), general purpose disinfectants (Oct. 1993), general surgical electrosurgical devices (Draft Oct. 19, 1993), daily wear contact lenses (Nov. 1993), *in vitro* devices (Draft 1994), arthroscopes and accessories (Draft May 1994), medical lasers (Draft Aug. 1994), biofeedback devices (Draft Aug. 1994), sharps safety devices (Mar. 1995), and 2-D laparoscopes (undated).

degree of FDA scrutiny that should be applied in evaluating this information.[45/]

Under its PMA/510(k) Triage Review Procedures, the FDA assigns submissions to one of three tiers, based upon the "inherent risk" of the device.[46/] Tier III is comprised of "all first and second of a kind devices utilizing new technology or having new intended use(s), as well as other PMAs and 510(k)s determined by their inherent risk to require an intensive review." Submissions for Tier III devices are subject to "[i]ntensive scientific and labeling review, using a team review approach." Tier II devices are deemed to pose less of an inherent risk. Section 510(k) and PMA submissions for Tier II devices are subject to "[r]outine scientific and labeling review." Tier I devices pose the lowest inherent risk. Accordingly, submissions for Tier I devices are subject to less scrutiny, consisting of "[e]ssentially a focused labeling review for intended use/indications for use." As the FDA has indicated, however, a review of the label indications and

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[45/] Thus, although certain substantial equivalence determinations for simple devices may require limited descriptive information regarding safety and effectiveness, "when the determination of substantial equivalence is based on an assessment of performance data, the supporting information is generally more voluminous and more complex." 57 Fed. Reg. 18062, 18063 (Apr. 28, 1992).

[46/] Memorandum from Susan Alpert (Acting Director, ODE) to ODE Review Staff regarding PMA/510(k) Triage Review Procedures (General Program #G94-1), at 2 (May 20, 1994) (hereinafter Triage Review Procedures). The Triage Review Procedures provide the flexibility to reassign device submissions among the tiers if information regarding the risk posed by a particular device merits such reassignment. *Id.* All quotations in this paragraph are from this document.

intended use of a medical device still constitutes an assessment of safety and effectiveness.[47/]

The level of safety and effectiveness review required by medical device manufacturers submitting section 510(k) applications also varies depending on the degree of risk posed by the device. Device manufacturers claiming substantial equivalence to a Class III device must conduct a more expansive review of safety and effectiveness data than must manufacturers of Class I or Class II devices.[48/] Under 21 C.F.R. § 807.87(i), such manufacturers must submit:

> a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94.[49/]

In the preamble to the interim rule establishing this requirement, the FDA explained why the search of adverse safety and effectiveness information must include all similar marketed devices:

> Limiting the class III summary and class III certification to adverse safety and effectiveness information known

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[47/] *See, e.g.*, 1986 Guidance, *supra*, at 5-6 ("For the purposes of determining whether or not the new device has the same intended use as a predicate device, the Center assesses any differences in label indications in terms of the safety and effectiveness questions they may raise.").

[48/] *See* FD&C Act § 513(f)(3), 21 U.S.C. § 360c(f)(3).

[49/] 21 C.F.R. § 807.87(i)(2); *see also* FD&C Act § 513(f)(3), 21 U.S.C. § 360c(f)(3).

> only about the device for which the premarket notification was submitted and a single predicate or legally marketed device is not consistent with *Congressional intent of ensuring that potential adverse safety and effectiveness concerns of that type of device are adequately addressed in a premarket notification.* This concern particularly applies in situations where there is limited clinical experience with the subject device.[50/]

C. The Labeling, Manufacture, And Design Of Medical Devices Are Regulated By The FDA Through The Section 510(k) Process And GMP Regulations.

1. Labeling

The FDA imposes labeling requirements for medical devices through the section 510(k) process. Because device labeling is essential to ensuring the safe and effective use of medical devices, section 510(k) submissions must include all labeling (*i.e.*, device labels, instructions for use, promotional material) for the device under review.[51/] If the FDA finds the submitted labeling inadequate or unsupported by information provided in the submission, the agency can request additional information to substantiate the proposed label claims or require the applicant to modify the labeling.[52/] The FDA may suggest alternative language, and often conditions a determination of substantial equivalence on the applicant's ability to resolve the safety or effectiveness issues raised by the agency.[53/]

[50/] 57 Fed. Reg. at 18064 (emphasis added).

[51/] 21 C.F.R. § 807.87(e); 1993 Guidance, *supra*, at 7.

[52/] *See, e.g.*, Appendix A.

[53/] *Id.*

2. Design and manufacture

Device design is essential to a determination of substantial equivalence. An evaluation of the technological characteristics of the medical device, including device design, historically has been the cornerstone of safety and effectiveness evaluations in the section 510(k) process. For example, the 1986 FDA guidance on the premarket notification review program explained that technological differences must be evaluated as a part of the substantial equivalence determination and that the section 510(k) submission must "explain why the device does not present new questions about safety or effectiveness, describe what accepted methods exist to test comparability of performance, and present data, generated from such tests, that demonstrate comparability."[54/]

As FDA explained in its interim rule to implement the provisions of the SMDA:

> FDA generally will require performance testing data to establish substantial equivalence if a new device has *different technological characteristics* than a predicate or legally marketed device, or when the descriptive characteristics of the devices are insufficient to ensure that the devices will perform comparably. In these cases, *performance testing data are necessary to demonstrate that the new characteristics of the device do not cause it to perform less safely or less effectively* than the legally marketed device to which it is being compared.[55/]

The FDA may also exercise control over the design of a medical device by refusing to grant marketing authority under section 510(k) based on certain identified technological characteristics of the device, which the agency determines

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[54/] 1986 Guidance, *supra*, at 8, 11.

[55/] 57 Fed. Reg. at 18063 (emphasis added).

raise concerns of safety or effectiveness. For example, in reviewing a section 510(k) application for a nerve locator/stimulator, the FDA found that the device was substantially equivalent to a predicate device.[56/] Based on a scientific evaluation of the device, however, the FDA found that certain aspects of the device's design rendered it unsafe. To address the FDA's concerns, the device manufacturer made specific design modifications to the medical device. Notably, this incident occurred in 1978, only two years after the effective date of the MDA and more than a decade before the SMDA was enacted.

As explained above, the FDA's GMP requirements comprehensively regulate the manufacture, release and postmarket surveillance of medical devices. In addition, the GMP regulations operate together with the section 510(k) substantial equivalence determination to impose specific design controls and requirements on medical devices.[57/] The FDA's draft guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device," provides guidance to manufacturers in determining when a change to a currently marketed device merits a new section 510(k) submission. The draft guidance explains how the section 510(k) premarket notification and authorization process and the GMP regulations operate together to assure that medical devices are safe and

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[56/] Relevant publicly available correspondence between the FDA and the manufacturer relating to this device is reprinted in Appendix B.

[57/] The FDA has proposed a new GMP regulation that will directly address design controls for new devices. *See* 58 Fed. Reg. 61952 (Nov. 23, 1993) (Proposed Rule); 60 Fed. Reg. 37856 (July 24, 1995) (Notice of Availability and Announcement of Public Meeting). As the FDA has stated, however, the current GMP regulation "is not silent on device design," by virtue of the design change and process validation requirements in the existing rules. FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device 2 (Draft #2 Aug. 1, 1995).

effective in their manufacture *and* design.[58/] The FDA explained that "[a]ny guidance on 510(k)s for changes to a marketed device must consider the role of the Good Manufacturing Practices (GMP) regulation in changes in device design."[59/] Responding to comments submitted regarding an earlier draft of the guidance, the FDA explained the interplay between the section 510(k) process and the GMP regulations in controlling device design:

> In this draft guidance, the reliance on design validation of changes under GMP is much more explicit, and, in many instances, the results of design validation activities are identified as indicators of when a change is significant enough to merit a premarket notification.[60/]

Thus, medical devices marketed through the section 510(k) process are not "frozen" technologically in a pre-1976 state. Rather, appropriate changes in manufacture and design continue to occur both before and after section 510(k) notifications are filed. These changes are all subject to the FDA's oversight to assure the safety and effectiveness of the new devices. Such incremental advances ensure that the quality of medical devices continues to improve over time.

II. PERMITTING STATE PRODUCT LIABILITY AND RELATED CLAIMS TO PROCEED AGAINST MEDICAL DEVICE MANUFACTURERS WOULD STIFLE INNOVATION AND IMPEDE THE AVAILABILITY OF IMPORTANT MEDICAL TECHNOLOGIES.

In enacting the MDA, Congress recognized that the application of state or local requirements to medical devices

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58/ *Id.*

59/ *Id.*

60/ *Id.* at ii.

would threaten technological innovation in the medical device industry. By placing the safety and effectiveness of medical devices exclusively in the FDA's authority, Congress struck a careful balance so that safety and effectiveness requirements would not hinder research and development of new medical devices.[61/] Congress decided that the FDA alone should regulate the safety and effectiveness of medical devices, without being second-guessed by lay juries in the 50 states.

Congress's concern is not unfounded. A 1988 report of the American Medical Association (AMA) Board of Trustees concluded that "[p]roduct liability is having a profound negative impact on the development of new medical technologies."[62/] The report explained:

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.[63/]

61/ *See* H.R. Rep. No. 853, at 12 (1976) (Congress enacted the MDA to protect public health and to ensure "innovations in medical device technology are not stifled by unnecessary restrictions"); S. Rep. No. 33, 94th Cong., 1st Sess. 2 (1975) (the MDA was intended both to encourage the research and development of "sophisticated, critically important medical devices" and to give the FDA the authority necessary to ensure public health and safety).

62/ AMA, *Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (June 1988) (hereinafter *AMA Report*).

63/ *Id.*

A. The Imposition Of Awards Against Medical Device Manufacturers Under State Law Would Impede The Development Of Important Medical Technologies.

A 1993 Institute for Civil Justice (ICJ) report noted: "Innovation is of social concern because of its potential to enhance future product safety and effectiveness and to reduce health care costs."[64] The ICJ report emphasized that "[e]ffects on innovative effort may be the most important element of the effects of liability on the economic performance of these industries."[65] Another report echoed this sentiment: "The result of this liability expansion has been a slowing of innovation in entire fields of inquiry, especially those having to do with health care."[66]

The ICJ report explained that while "[t]he economics of the industry impel companies to innovate, . . . liability concerns may steer them away from some types of innovation that appear to pose relatively large liability threats."[67] Unfortunately, the product areas with the largest potential

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[64] Steven Garber, *Product Liability and the Ec nomics of Pharmaceuticals and Medical Devices* 142 (1993). This report is based on a study conducted by Steven Garber, supported by the Institute for Civil Justice. RAND, the publisher of the report, is a nonprofit institution that seeks to improve public policy through research and analysis.

[65] *Id.*

[66] Richard J. Mahoney & Steven E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, Science, Dec. 15, 1989, at 1395, 1397; *see also* Peter W. Huber, *Liability* 160 (1988) ("Whatever intuition may tell us, newer is generally safer than older in the modern technological world. Slowing the pace of innovation did not advance safety in the least; it set it back sharply.").

[67] Garber, *supra*, at 144.

liability are often those with the greatest potential public health benefits, such as life-saving technologies.

B. The Imposition Of State Awards Would Threaten The Availability Of Critical Medical Technologies.

Product liability awards can have a significant impact on the availability of valuable medical technologies. As the ICJ report noted, the possibility of large liability and defense costs "can create enormous uncertainty for companies no matter how responsible their behavior."[68]

1. Useful products have been withdrawn because of liability concerns.

Biomaterials are natural or synthetic materials that are used in medical devices that will be in contact with body fluids, tissues, or both. Biomaterials are essential to a variety of life-saving and life-quality-enhancing medical devices. Because of product liability exposure, however, companies have been discouraged from pursuing the research, development and supply of biomaterials.[69] Research in the biomaterials field has "contributed to lifesaving technological advances, such as treatments for defective heart valves, hydrocephalus, failing heart rhythms, detached retinas, and other medical problems."[70] Determining that the liability

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[68] *Id.* at 91 (footnote omitted).

[69] *FDA Regulation of Medical Devices, Including the Status of Breast Implants, Joint Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations and the Subcomm. on National Economic Growth, Natural Resources, and Regulatory Affairs of the House Comm. on Government Reform and Oversight*, 104th Cong., 1st Sess. 181-182 (Aug. 1, 1995) (statement of James S. Benson, Senior Vice President for Technology and Regulatory Affairs, HIMA) (hereinafter Benson Statement).

[70] James S. Benson, *Biomaterials*, Med. Device & Diagnostic Indus., April 1995, at 34.

exposure is too great, many biomaterials suppliers either have withdrawn particular biomaterials from the medical device market or have left the device market altogether.[71] As a result, manufacturers of critical medical devices are having difficulty obtaining the raw materials vital to their products.[72]

The biomaterials shortage could have a devastating impact on patient care, restricting the availability of medical devices over "the entire spectrum of medical specialties, from cardiology and neurology to urology and ophthalmology."[73] The medical devices thus imperiled include heart valves, vascular grafts, pledgets (surgical tools), and intraocular lenses.

Products liability exposure for biomaterials manufacturers has particularly threatened the availability of life-saving hydrocephalus shunts.[74] Among other things, hydrocephalus shunts are used for draining the build-up of cerebrospinal fluid from the brains of affected infants or adults.[75] Approximately 75,000 of these shunts are implanted annually.[76]

An essential component of hydrocephalus shunts, silicone, has been particularly targeted by product liability claims.[77] Numerous other products rely on the availability of silicone, including arthroplasty devices (artificial joints), catheters,

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[71] Benson Statement, *supra*, at 181.

[72] *Id.*

[73] *Id.* at 182.

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *See* Gregory M. Lee, *The Use of Silicone as a Biomaterial*, Med. Device Technology, April 1995, at 20.

intravenous drip systems, cardiac pacemaker leads, implantable infusion pumps, wound drainage sets, ostomy systems, and several different types of grafts. Potentially enormous liability exposure has driven some silicone manufacturers out of the market, placing the availability of these critical medical devices at particular risk.[78]

Polyester (PET) yarn provides another example of a biomaterial whose availability is threatened by product liability exposure.[79] PET yarn has been used for permanent implants since the 1950's, and "is considered a highly reliable, safe material used as a standard building block by permanent implant manufacturers."[80] Because of product liability exposure, however, both domestic and foreign manufacturers have been discouraged from supplying PET yarn for use in the permanent device implant market.[81]

Product liability awards, or the threat of such awards, have impeded the availability of other medical devices as well. According to one source, product liability exposure caused the "sole domestic manufacturer of anesthesia gas machines" to stop producing these devices in 1984, "leaving the market to two foreign competitors."[82] Also influenced by liability concerns, one company "has foregone developing a suitcase-sized kidney dialysis unit and offering intravenous equip-

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[78] *Id.*

[79] *See* Aronoff Associates, Market Study: Biomaterials Supply for Permanent Medical Implants (March 1994). The Aronoff study was commissioned by HIMA to examine three materials, including PET yarn.

[80] *Id.* at 9.

[81] *Id.* at 14.

[82] Mahoney & Littlejohn, *supra*, at 1397.

ment."[83] Product liability exposure also may threaten the availability of infant sleep apnea monitors.[84]

2. Liability awards would impose social costs, with no countervailing public benefits.

Referencing the "profound negative impact" that product liability issues have on the "development and utilization of potentially life-saving medical technologies," the AMA stated: "Laws developed to protect the public at large can sometimes hurt the very individuals they were meant to protect."[85] This is certainly true where state product liability awards are imposed on manufacturers of FDA-regulated medical devices. "Capable of managing the uncertainties of research but not the uncertainties of law, companies have no choice but to avoid the courtroom by withdrawing products, keeping others off the market, and restricting the scope of research and development at its earliest stages."[86] The imposition of product liability produces no apparent public benefit to counterbalance its detrimental effects:

> Arguments that the proliferation of liability suits are somehow related to an increase in unsafe products are also not supported by facts, as no relation can be found between the two. Priest concludes that "data on deaths and injuries cast great doubt on the proposition that the liability crisis derives from an increase in the underlying accident rate" and "provide no evidence that the

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[83] *Id.*

[84] Kevin M. Quinley, *Avoidance: Dodging the Liability Bullet,* Med. Device & Diagnostic Indus., June 1991, at 44. Mr. Quinley is the Senior Vice President for Risk Services at Hamilton Resource Corp. and MEDMARC.

[85] *AMA Report, supra*, at 12.

[86] Mahoney & Littlejohn, *supra*, at 1395.

> expansion of litigation has affected the injury or death rate."[87]

The imposition of product liability awards on medical device manufacturers under state law may carry other, less apparent, social costs as well. For example, such actions might impair the practice of medicine by inappropriately influencing a physician's prescribing decisions.[88]

Thus, product liability awards deter important research and development activities in the medical device field and impede the availability of valuable medical technologies in a myriad of ways. Recognizing the serious detrimental effects that product liability exposure would have on the advancement of medical device technology, Congress wisely placed regulation of the safety and effectiveness of medical devices solely within the FDA's expert authority.

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[87] *Id.* at 1396 (citations omitted).

[88] Garber, *supra*, at 36.

CONCLUSION

The judgment of the court of appeals should be reversed in part as requested in Medtronic's petition in No. 95-754 and remanded with directions to affirm the judgment of the district court.

Respectfully submitted,

Of Counsel:

DONNELLDA RICE
General Counsel
Health Industry
Manufacturers Association
1200 G Street, N.W.
Washington, D.C. 20005
(202) 783-8700

BRUCE N. KUHLIK
Counsel of Record
JENNIFER A. JOHNSON
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1201 Pennsylvania Ave., N.W.
Washington, D.C. 20044
(202) 662-6000
Counsel for Health Industry Manufacturers Association

PAUL J. MALONEY
WILLIAM J. CARTER
SAMUEL J. SMITH, JR.
Carr, Goodson, Lee & Warner
1301 K Street, N.W.
East Tower - Suite 400
Washington, D.C. 20005-3300
(202) 310-5500
Counsel for MEDMARC Insurance Company, Inc.

March 13, 1996

APPENDICES

APPENDICES

APPENDIX A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

DEC 18 1989

Pekka T. Sipila, M.D.
Noraxon USA Inc.
8381 E. Gelding Drive
Scottsdale, Arizona
85260

Re: K895635
Myosystem 1000
"Electromyograph"
Dated: September 11, 1989
Rec'd: September 19, 1989

Dear Dr. Sipila:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. In order for us to complete the review of your submission, we require the following information:

1. You must provide proof of pre-Amendments commercial marketing of the Myoexorciser 1000 by Verimed, if you intend to use this as the comparison device for demonstrating substantial equivalence. You must provide a point by point comparison of the intended uses of your device to the device to which you are claiming substantial equivalence.

2. You must revise the promotional materials for the Myosystem 1000 to delete the following claims:

a. diagnosing muscular diseases, paralysis, rheumatism and spasms and measuring rehabilitation progress;

b. analyzing a single action cycle of one muscle and provide wave form analysis, e.g., during maximum weight lifting;

c. monitoring strength, power, speed, endurance, coordination, and reaction time in for sports medicine training;

d. measuring muscle loading and the quality of work conditions, tool designs, and working techniques development in work ergonomics/occupational medicine;

e. analyzing rhythmics to compare temporal values of successive action cycles with each other;

f. analyzing coordination of any two muscles;

g. monitoring success of rehabilitation program; and

h. measuring an athlete's EMG activity throughout performance.

Otherwise, you must include proof of pre-Amendments commercial marketing of EMG biofeedback devices for these intended uses and valid scientific data substantiating these claims.

3. You must label the Myosystem 1000 as a prescription device.

4. If you submit additional information that sufficiently addresses the above concerns, then you will need to submit a point by point comparison of the technological characteristics of the Myosystem 1000 and the device to which you are claiming substantial equivalence. This must include, but should not be limited to:

   a. sensitivity range(s) and accuracy;

   b. low noise amplifier:

      i. input noise;

      ii. differential Input Impedance;

      iii. input current;

      iv. common mode rejection ratio;

   c. notch filter;

   d. filter bandpass and rejection levels; and

   e. accuracy of each type of EMG display accuracy.

5. You must clarify each of the main functions that are performed and how they are performed, e.g., endurance analysis, rhythmics analysis, coordination analysis, etc.; enlarging sample diagrams/waveforms and more complete labeling of these enlargements might be useful. All columns must be identified on the analyses printout, e.g., sample rhythmics analysis. Definitions of all terminology (e.g., maxima, minima, etc.) and explanations of the results from the must be included. The names of these functions must be revised to be consistent with the labeling changes noted in #2

above. This information and revisions must be included in the user's manual.

6. You must explain why the endurance analysis requires a submaximal performance of a single muscle and how the clinician is to account for the variation in the amount of contraction provided with each successive repetition.

7. You must clarify whether or not the EMG signal (raw or integrated) is superimposed onto a grid; if not, how can the clinician check the accuracy of the coordinates?

8. You must explain why you are recommending that the integrated curves be smoothed and explain how this affects the accuracy and overall analysis.

9. You must delete claims that the signal is free of distortion within the EMG frequency domain and that the Myosystem 1000 only picks up the actual EMG activity and does not distort this signal in the process.

10. You must substantiate the claim that EMG signals as weak as 0.01 microvolt pose no problem for the instrument.

11. You must provide additional information regarding the software as follows:

    a. You must provide a description of how each main function is performed, i.e., clarify how the results are generated.

    b. Provide a brief narrative which explains the methods and procedures used for software validation and verification throughout the software

development lifecycle and software maintenance once the device is in commercial distribution.

    c. Explain the safety measures incorporated within the system to protect the user/patient in the event of a software failure.

    d. Describe the recommended user practices for monitoring system performance.

    e. Can the user change the software of the device and, if so, are there any limitations/controls on these changes? Is the software protected from inadvertent changes/deliberate tampering?

12. You must clarify whether the device design conforms to any voluntary standards, e.g., UL-544, and specify how it conforms. Specify how the device is isolated from each accessory device with which it interfaces, and whether the channels are isolated from each other.

13. Provide a point by point comparison of the technological characteristics for each accessory (included in this premarket notification submission) and for a comparison device, including but not limited to:

    a. materials and construction of each accessory, e.g., electrode cables, electrode adapters, system cable, surface and needle electrodes, electroconductive medium, printer, etc.

    b. electrical specifications of each powered accessory, including but not limited to power source, current leakage values, line isolation methods, etc.; and

c. clarification as to whether the device design conforms to any voluntary standards, e.g., UL-544.

d. information on the method of sterilization, the level of sterilization, the method of testing to assure compliance with this method and level of sterilization, and an explanation of why the method used does not damage the materials used in the construction of the needle electrodes, if needle electrodes are provided;

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact J. Blackwell, D.V.M., M.P.H., at (301) 427-1036.

Sincerely yours,

s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

January 23, 1985

E. Aubrey Woodroof, Ph.D.
President
Woodroof Laboratories
3100-7 Harvard Street
Santa Ana, California
92704

Re: K844052
BIOBRANE™ Brand
Temporary Wound
Dressing
with Adhesive Strip
Dated: September 28, 1984
Received: October 18, 1984

Dear Dr. Woodruff:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns or for use on full thickness skin wounds of any nature without specific Food and Drug Administration (FDA) approval for such labeling.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization without evidence of said effect being reviewed and approved by the FDA.

3. This device may not be labeled as a long-term or permanent, no change dressing, or as an artificial or synthetic skin without specific FDA approval for such labeling.

4. This device may not be labeled for use on vascular stasis ulcers without specific FDA approval for such labeling.

The labeling submitted does not comply with the above limitations. We suggest that you make the necessary changes in the labeling, and that before marketing the device in this country, you submit the revised labeling for review to the Division of Compliance Operations (HFZ-320) at the address noted below. If you are notified that the revised labeling is satisfactory, you may begin marketing your device subject to the general controls imposed by the Act.

You may market your device until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the FDA will be published in the FEDERAL REGISTER. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

s/
Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

NOV 6, 1989

Mr. Juergen F. Kopf
Vice President
Nemectron
28069 Diaz Road
Unit A
Temecula, California
92390

Re: K895000
Nemectron Microwave
Dated: July 28, 1989
Received: August 8, 1989

Dear Mr. Kopf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. In order for us to complete the review of your submission, we require the following additional information and changes to the labeling:

1. Your brochure shows application over the pelvis. Shortwave diathermy should not be applied to the gonads and therefore, this application must be deleted both explicitly or implicitly in any material relating to this device. A statement must be added to the contraindications section of your labeling which states, "Shortwave diathermy should not be applied to the gonads or to the developing fetus."

2. The following contraindications must be added to the operating manual:

(a) treatment of patients wearing IUD's containing copper or other metals;

(b) treatment of unconscious patients; and

(c) for local healing of ischemic tissues.

3. The statement "Any type of high frequency treatment of neoplasms should be supervised. . ." must be deleted. Neoplasms should not be treated by shortwave diathermy.

NOTE: ALL LABELING MUST COMPLY WITH DRAFT GUIDANCE DOCUMENT "PROPOSED GUIDELINES FOR LABELING OF SHORTWAVE DIATHERMY DEVICES FOR THERAPEUTIC PURPOSES" (copy enclosed).

4. State the peak and average power for all settings for each output mode.

5. Do all device settings produce 40-45°C heat in deep tissues?

6. Are the generator and cables impedance matched to the applicators?

7. Does the device meet stray radiation standards? How is the stray radiation measured and what are the values reported?

We believe that this information is necessary for us to determine whether or not this device is substantially

equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Michael J. Blackwell, D.V.M., M.P.H., at (301) 427-1036.

Sincerely yours,

s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUL 31 1986

Mr. Magnus Ahlen
President
Suntec Health & Fitness
Group, Inc.
P.O. Box 2668
Westport, Connecticut 06880

Re: K862293
Electro Trim
Dated: April 1, 1986
Received: June 17, 1986
Regulatory Class: II

Dear Mr. Ahlen:

Your Section 510(k) notification of intent to market the above-referenced device has been reviewed. We have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments.

However, we would regard the Electro Trim to be misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act (Act) due to its misleading name, and the labeling you submitted. Muscle stimulators, regardless of design, are considered to be prescription devices subject to labeling requirements of 21 CFR 801.109 (copy enclosed). Only the following intended uses are considered acceptable:

1. relaxation of muscle spasm;

2. prevention or retardation of disuse atrophy;

3. increasing local blood circulation;

4. muscle re-education;

5. immediate postsurgical stimulation of calf muscles to prevent venous thrombosis; and

6. maintaining or increasing range of motion.

We suggest that you make the necessary changes to the trade name and labeling before marketing this device and you submit such notification for review to the Division of Compliance Operations (HFZ-320). If you are notified that the revised labeling is satisfactory, you may begin marketing your device subject to the general controls provisions of the Act. This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so you can convey your views to the FDA if you desire and be notified of any additional requirements subsequently imposed on your device.

Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

s/
David L. West, Ph.D.
Associate Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

bcc:HFZ-401 DMC
HFZ-403 RChissler
HFZ-410 DSRD
f/t:HFZ-410/SLPhillips/bls/7/2/86
corr:bls/7/11/86

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

DEC 28, 1989

Mr. Lee Cole
President
American Hair Removal System
160 South May Street
Southern Pines, North Carolina
28387

Re: K892514
AHRS Epilator 629
Dated: September 28, 1989
Received: October 6, 1989

Dear Mr. Cole:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following additional information:

1. data to support your hair bulb pH measurements, including a description of the method, and a comparison to pH for plucked and conventionally epilated hairs, and references;

2. data to support the claim that your device delivers electrical current to the dermal papilla equivalent to that delivered by a marketed epilation device, including a description of and justification for the method used;

3. a comparison of the force, in pounds, required to remove hairs treated with your device and a marketed epilation device, including a description of the method used;

4. data from a clinical investigation, preferably according to Section IV of "Official Standards for the Treatment of Permanent Hair Removal" of the International Guild of Professional Electrologists, directly comparing the use of your device to a marketed epilation device; and

5. a full report of histological examination of the roots of hairs epilated with your device.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Mr. Roger W. Barnes at (301) 427-1090. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely, yours,

s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

JAN -9 1987

Mr. J. N. Upton
Rapidex
16 Jacobs Well Mews
George Street
London W1H 6BD, England

Re: K862282A
Rapidex Biological Surfactant
Dated: October 23, 1986
Received: October 30, 1986

Dear Mr. Upton:

This is in response to your 510(k) premarket notification submission for the above referenced device. In order to complete our review of your submission, we need the following additional information:

1. A draft copy of all labeling that will be used in the United States. The claims for the product must reflect what the user would expect from Rapidex when following the instructions for use. The present instructions for use are for a concentration of 1.75 ounces of Rapidex per 1.5 gallons of water at room temperature for a 5 minute contact time and, implied, under sterile conditions. If the claims are based on other use conditions, such as saline instead of water, higher temperatures, and/or different concentrations of Rapidex, these conditions must also be listed in the labeling. For

example, if specific use conditions are required to kill certain microorganisms, these conditions must be identified in the labeling for each specific or group of organisms.

Based on the information and the data that you have previously submitted, Rapidex can be considered as a surfactant with bacteriostatic activity. The data indicate that Rapidex may have some limited bactericidal action against gram negative organisms and little action against some gram positive organisms. Data from the single test on HTLV III/LAV/HIV viruses are not enough to support a general viricidal claim for Rapidex. The data do not support claims that Rapidex is fungicidal.

2. A copy of the "User Leaflet" which contains full instructions for the use of Rapidex for the customers in the United States.

3. A copy of the draft label that is planned to be used on the sachet sold in the United States.

4. Detailed information on the laboratory method used to test the viricidal action of Rapidex on HTLV III/LAV/HIV viruses. Also detailed results of the viricidal testing that was performed on the viruses.

5. The name and description of the a product similar to Rapidex to which you claim substantial equivalence, that was sold in the United States prior to May 28, 1976.

The additional information should be submitted, in duplicate, referencing the 510(k) number above, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have any questions concerning your 510(k) submission, please contact Mr. George Mills, General Hospital and Personal Use Devices Branch, at the above address or at (301) 427-7750.

Sincerely yours,

s/
Fernando Villarroel, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices (HFZ-420)
Office of Device Evaluation
Center for Devices and
Radiological Health

APPENDIX B

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20910

DEC 7 1978

Mr. J. R. Moore
Manager
Corporate Regulatory Affairs
Intermedics, Inc.
Box 617
240 Tarpon Inn Village
Freeport, TX 77541

Ref: K781569A - Nerve Locator/Stimulator

Dear Mr. Moore:

Your Section 510(k) notification of intent to market a direct current nerve locator/stimulator has been reviewed. We have determined the device to be substantially equivalent to another direct current nerve locator/stimulator marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976.

However, our scientific staff informs me that the application of direct current to an exposed nerve by means of this device may injure the nerve thereby causing a paralysis. Based on an electrode of 0.03 inch diameter with a minimum output current of 0.5 milliamperes a charge density of 500 microcoulombs per cm^2 will be reached within 5 milliseconds. A charge density of 500 microcoulombs per cm^2 has been demonstrated to cause an alkaline pH shift and hydrogen gas production at the stimulating electrode which can result in lesion of the nerve

tissue. To date we have seen no documentation which contradicts this finding.

Because it is not possible to accurately regulate by manual control, the period of time a patient is exposed to this device, we believe that your device may be unsafe for its intended purpose.

In view of this, we would appreciate receiving from you any data which demonstrates that your device is safe for its intended use, or that our opinion in this matter is incorrect. You should be aware that if we determine your device is unsafe, and the device has been marketed, your device may be subject to the appropriate sanctions offered by the Federal Food, Drug, and Cosmetic Act.

Please contact Dean A. Barlow, Division of Compliance Operations, Bureau of Medical Devices, 8757 Georgia Avenue, Silver Spring, Maryland 20910 with your reply to this letter as soon as possible.

Sincerely yours,

s/
David M. Link, Director
Bureau of Medical Devices

SURGITRONICS
Tarpon Inn Village • P.O. Box 616
Freeport, Texas 77541 • (713) 233-0201

December 28, 1978

Mr. Dean A. Barlow
Division of Compliance Operations
Bureau of Medical Devices
8757 Georgia Avenue
Silver Springs, Maryland 20910

Dear Mr. Barlow:

This letter is in reply to your request for information on the safety of our disposable nerve locator/stimulator. In a spirit of cooperation and good faith, we stopped production of these devices shortly after receipt of your letter.

We have reviewed the scientific articles that Mr. J. R. Veal provided as references. Appendix A summarizes our arguments regarding the safety of the existing nerve locators.

We have decided to add a series capacitive coupling network to the existing circuitry which limits the period of time that the nerve locator delivers stimulation current to body tissue. The decision to add the coupling network was made because the operation of the device will be improved since the potential of damage to nervous tissue by misuse of the product by physicians has been reduced; and also because a long and expensive debate with your agency on this subject would not benefit anyone. Appendix B lists the

circuitry and performance graphs of the nerve locator with capacitive coupling.

After your scientific staff has reviewed our data in Appendix B, please contact me as soon as possible regarding their opinions and the necessity to file additional or supplemental 510(K) reports with your agency.

Sincerely yours,

s/
Steven A. Barton
President

SAB:bw

Enclosures

cc: Mr. Alfred B. Beers
Executive Vice President
Intermedics, Inc.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20910

January 24, 1979

Mr. Steven A. Barton, President
Surgitronics
Tarpon Inn Village
P.O. Box 616
Freeport, Texas 77541

Ref: K781569

Dear Mr. Barton:

This is in response to your letter of December 28, 1978, and follow-up telephone calls regarding the Nerve Locator and Stimulator.

Your submission dated December 26, 1978, Appendix A-B of the Intermedics Disposable Nerve Locator Models 554-01/2 has been reviewed and we offer the following comments.

In our December 7, 1978, letter regarding the status of the devices we raised specific objection to the application of direct current in a manner which could cause paralysis. Your modifications as listed in Appendix B would appear to have corrected the objectionable operational characteristics of the original nerve locator. We, therefore, have no objection to the marketing of this modified device.

You are also advised that an additional 510(k) submission for the model 554-02 will not be necessary. You have discussed this with Mr. Veale by phone recently and he concurs that the proposed future modification to the 554-02 would not be significant enough to warrant the submission of another 510(k).

We have been requested to furnish a copy of this letter to Mr. Redner, however, we are electing to limit this correspondence to you. Whether you send a copy to Mr. Redner is your choice.

Should there be any further questions please contact this office directly.

Sincerely yours,

s/
Dean A. Barlow
Division of Compliance Operations
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Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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Brief For The Medical Device Manufacturers Association As *Amicus Curiae* Supporting Petitioner/Cross-Respondent Medtronic, Inc.

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TABLE OF CONTENTS

	Page
STATEMENT OF INTEREST	1
SUMMARY OF ARGUMENT	2
ARGUMENT	3
I. THE MEDICAL DEVICE INDUSTRY RETAINS THE NATURE THAT LED CONGRESS TO PREEMPT STATE MEDICAL DEVICE REQUIREMENTS	4
II. APPLICABLE FEDERAL REQUIREMENTS PREEMPT ALL OF PLAINTIFFS' CLAIMS	7
A. *FDA Requirements Applicable To Medtronic's Device Through Its Clearance For Marketing*	7
B. *FDA Post-Marketing Requirements Applicable To The Medtronic Device*	12
C. *FDA Enforcement Of Its Requirements*	16
III. FEDERAL PREEMPTION MAY NOT BE AVOIDED BY BASING STATE-LAW LIABILITY ON ALLEGED VIOLATIONS OF FDA REQUIREMENTS	18
A. *Consistent State Requirements Are Facially Preempted By §360k(a), And Congress Deleted Language Preserving Such Claims*	19
B. *Exempting Consistent State Requirements From Preemption Would Violate The Exclusive Enforcement Authority Of FDA*	23
C. *State-Law Non-Compliance Claims Cannot Possibly Impose Requirements Consistent With FDA's Requirements*	27
CONCLUSION	30

TABLE OF CONTENTS—*(Continued)*

Page

Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program (FDA Jun. 30, 1986) ..... App. A

Flow Chart Excerpted from, *HHS Publication FDA 95-4158, Premarket Notification 510(k): Regulatory Requirements for Medical Devices*, App. C at C-16 (U.S. Govt. Printing Off. Aug. 1995) ..... App. B

General Program Memorandum No. G91-1, Device Labeling Guidance (FDA Mar. 8, 1991) ..... App. C

FDA telefax with handwritten changes to proposed 510(k) labeling, Division of General and Restorative Devices (FDA Jan. 10, 1995) ..... App. D

Preemption Provisions Contained in Precursor Legislation To the MDA ..... App. E

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California v. Federal Energy Regulatory Commission, 495 U.S. 490 (1990) 25

Chadwell v. Optical Radiation Corp., 902 F. Supp. 830 (S.D. Ind. 1995)..... 26

Chicago and North Western Transportation Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981)..... 18,25,26

District of Columbia v. Greater Washington Board of Trade, 506 U.S. 125 (1992) 22

Duke v. American Medical Systems, Inc., 1995 WL 505472 (N.D. Ill. Aug. 18, 1995)..... 26

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Fender v. Medtronic, Inc., 887 F. Supp. 1326 (E.D. Cal. 1995)..... 26

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Ingersoll-Rand Co. v. McClendon, 498 U.S. 133 (1990) 23

John Hancock Mutual Life Insurance Co. v. Harris Trust & Savings Bank, 114 S. Ct. 517 (1993) 21

Kemp v. Pfizer, Inc., 835 F. Supp. 1015 (E.D. Mich. 1993) 26

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Martin v. Telectronics Pacing Systems, Inc., 70 F.3d 39 (6th Cir. 1995), *cert. pending*, 64 U.S.L.W. 3593 (U.S. filed Feb. 20, 1996) 29

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Mears v. Marshall, 905 P.2d 1154 (Or. App. 1995) 26

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Morales v. Trans World Airlines, Inc., 504 U.S. 374 (1992) 19,21,22,23

Niehoff v. Surgidev Corp., 1995 WL 794203 (Ky. App. Nov. 17, 1995) 26

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Reeves v. AcroMed Corp., 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995) 22,26

Richman v. W.L. Gore & Associates, Inc., 881 F. Supp. 895 (S.D.N.Y. 1995) 26

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Scott v. Ciba Vision Corp., 44 Cal. Rptr. 2d 902 (Cal. App. 1995) 26

Shaw v. Delta Air Lines, 463 U.S. 85 (1983) 22

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United States v. Sullivan, 332 U.S. 689 (1948)..... 25

Washington Legal Foundation v. Kessler, 880 F. Supp. 26 (D.D.C. 1995) 17

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Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539..... 21, App. E

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15 U.S.C. §2075(a)..... 19

15 U.S.C. §2617(a)(2)(B)..... 19

18 U.S.C. §3663(a)(1)..... 17

21 U.S.C. §332..... 16

21 U.S.C. §333(a)..... 16

21 U.S.C. §333(f)(1)(A)..... 17

21 U.S.C. §334(a)(2)(D)..... 16

21 U.S.C. §334(g)..... 16

21 U.S.C. §336 7,17,24

21 U.S.C. §337 7

21 U.S.C. §337(a)..... 24

21 U.S.C. §343-1(a)(1) 19

21 U.S.C. §351(h) 13

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21 U.S.C. §352(a)..... 17

21 U.S.C. §352(f)(1) 17

21 U.S.C. §352(j)..... 17

TABLE OF AUTHORITIES—*(Continued)*

Statutes: **Page(s)**

21 U.S.C. §360(k) 8

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21 U.S.C. §360c(i) 8

21 U.S.C. §§360c-360l..... 7

21 U.S.C. §360f 16

21 U.S.C. §360h 16

21 U.S.C. §360h(a) 17

21 U.S.C. §360h(b) 17

21 U.S.C. §360h(c)..... 17

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21 U.S.C. §360j(f)(1)(A)..... 17

21 U.S.C. §360k 21

21 U.S.C. §360k(a)..... 2,5,7,10,18 19,20,21,22,23 25,26,27,29

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21 U.S.C. §360k(a)(2)..... 22,23

21 U.S.C. §360k(b) 5,21

21 U.S.C. §360k(b)(2)(B)..... 23

21 U.S.C. §360ss..... 19

21 U.S.C. §374(a)..... 13

21 U.S.C. §374(e)..... 13

49 U.S.C. §30103(b) 19

TABLE OF AUTHORITIES—*(Continued)*

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21 C.F.R. §803.3(g) 14,16
21 C.F.R. §803.24 14
21 C.F.R. Part 807, Subpart E 8
21 C.F.R. §807.31(e) 14
21 C.F.R. §807.81(a) 8
21 C.F.R. §807.81(a)(3)(i) 15
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21 C.F.R. §820.1(a) 13
21 C.F.R. §820.3(f) 13
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21 C.F.R. §820.20(a)(2) 14
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21 C.F.R. §820.81(b) 13
21 C.F.R. §§820.100-.101 13
21 C.F.R. §820.100(a) 16
21 C.F.R. §820.101 13
21 C.F.R. §§820.115-.116 13
21 C.F.R. §820.116 13
21 C.F.R. §820.120 13,14
21 C.F.R. §§820.120-.121 13
21 C.F.R. §820.120(b) 13
21 C.F.R. §820.121 14
21 C.F.R. §820.121(a) 13
21 C.F.R. §820.121(b) 13
21 C.F.R. §820.130 13
21 C.F.R. §820.150 13
21 C.F.R. §820.151 13
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21 C.F.R. §820.185 13
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Legislative History:

121 Cong. Rec. 10688 (S. Apr. 17, 1975) 20
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Flow Chart Excerpted from, *HHS Publication FDA 95- 4158, Premarket Notification 510(k): Regulatory Requirements for Medical Devices* (U.S. Govt. Printing Off. Aug. 1995) ..... 10,App. B
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BRIEF FOR THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION AS *AMICUS CURIAE* SUPPORTING PETITIONER/CROSS-RESPONDENT MEDTRONIC, INC.

STATEMENT OF INTEREST

The Medical Device Manufacturers Association ("MDMA") is a national trade association of over one hundred mostly small manufacturers of medical devices, diagnostic products and health care information systems. To improve the quality of patient care, MDMA encourages development of new medical technology and availability of innovative products. MDMA therefore pursues its members' interests in the laws and regulations enforced by the United States Food and Drug Administration ("FDA"), including how those laws and regulations are interpreted and applied in the courts.

The decision in this case will profoundly impact MDMA's members. In the 1976 Medical Device Amendments ("MDA")

to the Federal Food, Drug and Cosmetic Act ("FDCA"), Congress expressly preempted all state legal requirements relating to medical devices that were different from, or in addition to FDA requirements. 21 U.S.C. §360k(a). A primary reason Congress did so was the adverse effect of dual state and federal medical device requirements on "small manufacturer[s] of medical devices"[1] — MDMA's membership. Twenty years later, this Court is being asked to upset this congressional policy by exempting from preemption a major source of state-imposed legal requirements, common law tort actions.

MDMA files this brief in support of petitioner/cross-respondent Medtronic, Inc. Written consents have been filed with the Clerk.

SUMMARY OF ARGUMENT

Cross-petitioners Lora and Michael Lohr (hereafter referred to as "plaintiffs") seek damages for personal injuries that they allege were caused by a cardiac pacemaker lead made by petitioner Medtronic, Inc. They claim the leads were defectively designed, manufactured, and assembled, and that Medtronic failed to provide adequate warnings and violated FDA requirements. The Court of Appeals held that all of these claims were preempted by the MDA except those relating to design. *Amicus* MDMA submits that the Court of Appeals failed to recognize the full extent of federal medical device regulation. Had the Court of Appeals understood how pervasive and detailed that scheme is, it would have held all of plaintiffs' claims preempted.

In the following argument *amicus* will first show that Congress understood that the distinctive nature of medical device production warranted exclusive federal regulation. Because the requisite federal oversight would burden what was and is an innovative industry populated by small companies with limited financial resources, Congress balanced the scale by preempting parallel state legal requirements.

1. S. Rep. No. 33, 94th Cong., 2d Sess. at 18 (1976) (reprinted at 1976 U.S.C.C.A.N. 1070, 1087).

Next, *amicus* will describe the federal regulatory scheme, demonstrating how it necessarily preempts plaintiffs' claims, including the design claim that the Court of Appeals held not preempted. Preemption flows from federal "requirements" — a broader term than "regulations" — so to decide this case, this Court must have before it the full scope of federal medical device requirements, including those imposed by the FDA's device clearance process, its extensive post-market requirements, and its enforcement activity.

Finally, *amicus* will explain why plaintiffs cannot escape federal preemption by bringing state-law claims that manufacturers violated requirements imposed by federal law. Congress deleted from the MDA a preemption exception that would have preserved this type of claim, and preemption reinforces both the statute's prohibition of private enforcement and grant of prosecutorial discretion to the FDA. Nor can state tort litigation be consistent with FDA requirements in practice, since any contested case would inevitably involve opposing interpretations of what those requirements are.

Amicus submits that the judgment of the Court of Appeals should be affirmed except insofar as it did not preempt plaintiffs' design-related claim. As to that claim, the judgment should be reversed, and judgment entered for Medtronic.

ARGUMENT

In enacting the MDA in 1976, Congress sought to protect public health by balancing the need for regulation of medical devices with the need for development of new and improved devices without excessive cost or delay.[2] A critical part of that balance — preemption of state legal requirements in favor of intensive FDA regulation of medical devices — is now before the Court.

2. *See* S. Rep. No. 33 at 5 (1976) ("Although many lives have been saved or improved by the new discoveries, the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the[ir] complicated technology"), at 6 (recognizing both "benefits that medical research and experimentation to develop devices offers" and a "need for regulation to assure that

I. The Medical Device Industry Retains The Nature That Led Congress To Preempt State Medical Device Requirements.

The MDA's legislative history is replete with Congressional recognition of the distinctive structure of the medical device industry. The industry's defining trait is constant innovation. "[T]he state of the art in the medical devices field is rapidly changing and continually improving." S. Rep. No. 33, 94th Cong., 2d Sess. at 11 (1976) (reprinted at 1976 U.S.C.C.A.N. 1070, 1081). Congress understood that "devices [are] subject to rapid obsolescence." *Id.* at 16 (reprinted at 1976 U.S.C.C.A.N. 1085). Accordingly, Congress "developed a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices . . . and that innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. at 12 (1976).[3] The MDA was drafted to foster innovation — "to permit new or improved devices to be marketed without delay so that the public may have such beneficial devices available to them as soon as possible." S. Rep. No. 33 at 14 (reprinted at 1976 U.S.C.C.A.N. 1083). Plaintiffs may disagree with how Congress struck its balance, but reweighing the interests involved is for Congress, not the courts.

NOTES *(Continued)*

the public is protected"), at 7 ("a balance [should] be struck between the need for continuing research and the need for improved patient protection"), at 13 (intent that "innovation is not stifled" and that " 'quack' devices or devices known to be unsafe or ineffective" not be allowed) (reprinted at 1976 U.S.C.C.A.N. 1074, 1075, 1076, 1083); H.R. Rep. No. 853, 94th Cong., 2d Sess. at 10 (1976) ("protection against unsafe, unproven, ineffective and experimental medical devices is counterbalanced by an equally strong conviction that excessive . . . regulation would stifle progress").

3. *See* S. Rep. No. 33 at 13 ("innovation"), 14 ("rapidly changing nature"), 15 ("stage of rapid development;" "rapidly changing") (citation and quotation marks omitted) (reprinted at 1976 U.S.C.C.A.N. 1083, 1084).

An inherent consequence of rapid innovation in any industry is the presence of many relatively small companies. Both the Senate and the House appreciated the impact of the MDA on the small enterprises that constitute the great majority of the medical device industry. The Senate took "specific note" of concerns about:

> the impact of this legislation on the small manufacturer of medical devices. The concern stemmed from the importance of the small innovative manufacturer in the invention and development of new medical devices and the inability of these firms, because of limited financial resources, to sustain the high level of administrative costs demanded of a highly regulated industry . . . .

S. Rep. No. 33 at 18 (reprinted at 1976 U.S.C.C.A.N. 1087). The Senate recognized "these concerns a[s] legitimate . . . consistent with the public's need for safe and effective medical devices." *Id.* It expressed "confiden[ce] that the administration of this new law will also take into account the need to preserve the small manufacturer's role in the device industry. *Id.* The House agreed:

> [The MDA] reflects the need to develop innovative new devices . . . . [I]t recognizes that this significant new authority must not unnecessarily burden the small manufacturers of medical devices who have been responsible for the development of a host of important and innovative devices.

H.R. Rep. No. 853 at 12. *See id.* at 56 ("cognizant of the potentially detrimental economic impact of this legislation . . . on small device manufacturers").

One way Congress ameliorated the potential undue burden upon small device manufacturers was to couple comprehensive federal regulation with preemption of state legal requirements. 21 U.S.C. §360k(a); *see* H.R. Rep. No. 853 at 45. Only if the FDA expressly found that a state requirement "would constitute a useful supplement to federal regulation," H.R. Rep. No. 853 at 45, could any state legal requirement be exempted from preemption. *See* §360k(b).

The concerns motivating Congress in 1976 remain valid today. Congress heard testimony about the current structure of the medical device industry on March 30, 1995:

> There are approximately 5,000 distinct generic types of devices and more than one million brands, models and sizes. . . . In the United States, this disparate collection of entities is produced by approximately 5,000 manufacturers. The vast majority of U.S. device manufacturing firms are quite small and very specialized and have fewer than 50 employees. There are relatively few large national or multinational manufacturers. . . .

H.R. Serial No. 18, 104th Cong., 1st Sess. at 22 (Mar. 30 1995) (statement of Joel J. Nobel, M.D.).[4] Rapid innovation limits the life cycle of medical devices, providing only a short time for recouping development expenses and achieving profitability:

> Most devices are typically developed in 1 to 3 years, become obsolete, and are off the market in 3 to 7 years. This temporal distinction is critical. . . . When approval time consumes almost half of the product's life cycle, something is seriously out of balance. . . . The consequences of approval delays may impact patients, as well as manufacturers and investors, negatively.

H.R. Serial No. 18 at 26 (Dr. Nobel) (emphasis omitted).

As the FDA's medical device requirements have become increasingly comprehensive and detailed, the financial burden of compliance has similarly grown.[5] Federal preemption of

4. *See 1994 Reference Guide for the Health Care Technology Industry* at 4 (Health Care Technology Institute 1994) (72.1% of FDA-registered device manufacturers had under 50 employees and 96.4% had fewer than 500 employees).

5. Small device manufacturers need venture capital to finance new products, but they "face[] increased challenges in attracting venture interest as a result of FDA's expanded efforts to govern market clearance for medical devices." *Trends in Venture Capital Funding for the Medical Device Industry* at 3 (Health Care Technology Institute Mar. 1994). A "growing" number of "regulatory hurdles in the path of innovation" have contributed to a recent decline in venture capital investment in the medical device field. *1995 Reference Guide for the Health Care Technology Industry* at 15 (Health Care Technology Institute 1995). *See also* H.R. Serial No. 18 at 53 (34% venture capital decline in 1993; also describing decline in public offerings by device companies between 1992 and 1995) (statement of Ali Gallagher).

state law is thus more important than ever to small device manufacturers. It is the most significant way that Congress alleviated the financial burden of its all-encompassing federal regulatory scheme.

II. Applicable Federal Requirements Preempt All Of Plaintiffs' Claims.

The 1938 FDCA dealt mostly with food and drugs. The federal government received exclusive enforcement authority and discretion to decide whether and how to prosecute violations. 21 U.S.C. §§336-37. The 1976 MDA expanded the FDA's power, giving the Agency comprehensive regulatory authority over medical devices. *See generally* 21 U.S.C. §§360c-360l. The MDA did not dilute either sole federal enforcement authority or federal prosecutorial discretion.

The MDA gives preemptive force to any federal requirement that "relates to" either device "safety or effectiveness" or to "any other matter included in a requirement applicable to the device." §360k(a). Congress used the broad term "requirement" in preference to "regulation" or other more narrow language. *See, infra,* at 20 & n. 29. Thus, application of preemption must reflect not only FDA's formal regulations — extensive in their own right — but also FDA requirements not contained in regulations. *See* 42 Fed. Reg. 30383, 30384 (FDA Jun. 14, 1977) (preemption may arise from "regulatory or administrative action").

A. *FDA Requirements Applicable To Medtronic's Device Through Its Clearance For Marketing*

The regulatory status of the Medtronic cardiac pacemaker lead at issue in this case is undisputed — the FDA cleared it for marketing via a process called "510(k)" pre-

market notification. *See* 21 U.S.C. §360(k) (§510(k) of the MDA); *see also* §360c(f,i) (detailing 510(k) criteria). The FDA can clear any device (of any classification[6]) through this process by finding it "substantially equivalent" to a device (called a "predicate device") that either: (1) was in commercial distribution prior to passage of the MDA in 1976, or (2) is otherwise being legally marketed. *Id.;* 21 C.F.R. §807.81(a). Absent an FDA exemption, the MDA mandates that these 510(k) "requirement[s]" remain "applicable to a device." 21 U.S.C. §360j(a) (referencing §360(k)). There is no such exemption here, so the 510(k) clearance process is one source of preemptive requirements applicable to this device.

Manufacturers seek 510(k) clearance by submitting "premarket notifications" to the FDA. These must contain: (1) proposed labeling; (2) a statement of design similarities and differences compared to the predicate device; (3) a description (which may include photographs and engineering drawings) of significant physical and performance characteristics of the device, including its design, materials and physical properties; (4) the medical conditions for which the device is "intended" to be used; (5) information showing how the "design, material, chemical composition, or energy source" of the device is substantially equivalent to the predicate device, and (6) "[a]ny additional information" the FDA requires to determine substantial equivalence. 21 C.F.R. §§807.87(e-h); 807.92(a)(4-6).

Some of these 510(k) criteria were formally "codified" in 1990,[7] but all existed as FDA requirements well before that time. A 1986 FDA guidance document (reproduced as Appendix "A") "outlines requirements for premarket notification review" for "consistent application" by Agency reviewers.

6. The FDA assigned Class III status to the Medtronic pacemaker leads. *See* 21 C.F.R. §870.3680. 510(k) clearance imposes essentially the same requirements upon any device, regardless of its resulting classification. *See* 21 C.F.R. Part 807, Subpart E; M. Herrmann & G. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 Food & Drug L.J. 1, __ (1996) (forthcoming).

7. *See* H.R. Rep. No. 808, 101st Cong., 1st Sess. at 24 (reprinted at 1990 U.S.C.C.A.N. 6305, 6317) (1990 Safe Medical Devices Act "codifies FDA's current practice regarding the use of the 510(k) procedure").

App. "A" at 1a. This guidance document elaborates the extensive requirements that 510(k) clearance imposes on both device design and labeling:

- Manufacturers must "compare[] the new device to a marketed device of a similar type." App. "A" at 4a.
- This comparison must include "technological characteristics, (i.e., same materials, design, energy source, etc.)." *Id.* at 6a.
- All changes to "technological characteristics" must be evaluated by "accepted scientific methods" to determine if they raise "new questions" about safety or effectiveness. *Id.*
- The "therapeutic or diagnostic statements" in the labeling and promotional materials for both the predicate and new devices must demonstrate the same "intended use" for both devices. *Id.* at 7a.
- The manufacturer must demonstrate the same intended use and that "any changes in labeling are immaterial." *Id.* at 10a.
- The FDA conducts a detailed evaluation of design changes in determining whether to grant 510(k) clearance. *Id.* at 10a-11a.[8]
- The FDA "always require[s] descriptive data. . .[concerning] a new device's intended use, physical composition, method of operation, specifications, performance claims, etc." *Id.* at 16a.

8. The 1986 guidance document cites examples of actual FDA evaluations of device design changes: modified visual displays for electrocardiographs, modified connector designs for penile prosthetic pumps, substitution of computerized features for manually operated features, substitution of one type of filtration membrane for another, "minor change[s] in design" of heart valve shape and composition, use of electrical shocks versus sound waves for kidney stone fragmentation, and smooth versus contoured surfaces for hip implants. *Id.* at 10a-15a.

- If there is "an important descriptive difference," the FDA will normally require performance testing data. *Id.*[9]

As the FDA's 1986 guidance document illuminates, 510(k) clearance involves a complex and detailed FDA evaluation of both the design and labeling of medical devices. In its searching clearance inquiry, the FDA frequently calls for "additional information." 21 C.F.R. §807.87(h). Compliance with such requests is mandatory or the FDA "consider[s] the premarket notification to be withdrawn." *Id.*[10] To explain the complicated operation of 510(k) clearance, the FDA has prepared a detailed "flow chart" describing the process. The FDA's flow chart is reproduced at Appendix "B".[11]

The Court of Appeals limited its consideration to the FDA's regulations. It failed to consider how, in practice, the FDA imposes design-related requirements through the 510(k) process. The Court of Appeals erred when it concluded that state-law tort claims challenging device design were not preempted as "different from or in addition to" "requirement[s]" imposed by 510(k) clearance. §360k(a).

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9. Pacemaker leads — the device at issue in this case — are cited in the FDA guidance document as an example of when performance testing data is required by the 510(k) process. *Id.* at 17a.

10. The record contains Medtronic's affidavit listing the additional information FDA required here. Swanson Aff. ¶8. Other examples of "additional information" that the FDA has demanded from MDMA's members include: engineering drawings; fatigue and other test results; sterilization methods, including process validation of such methods; identification of other devices with which a device may be used; lists of the applicant's previously cleared devices; dimensional comparisons with the predicate device; performance information; device samples; design and intended use memoranda; "worst case" scenarios; drawings or descriptions of how multicomponent device systems are assembled; photographs of devices in use; enlarged photographs; ASTM materials standards; profile analysis for implantable devices; surgical technique manuals; descriptions of device packaging; lists and descriptions of instruments to be used with devices; and summaries of information supporting safety and effectiveness.

11. The flow chart is from HHS Publication FDA 95-4158, *Premarket Notification 510(k): Regulatory Requirements for Medical Devices*, App. C at C-16 (U.S. Govt. Printing Off. Aug. 1995).

A second FDA guidance document, No. G91-1 (reproduced at Appendix "C"), enumerates 510(k) requirements for device labeling. This document serves two purposes: "formal[] guidance to [FDA] reviewers concerning their review of labeling in device marketing submissions" and "for industry use in preparing device labeling." App. "C" at 1c. Guidance document G91-1 further shows the extensive labeling requirements imposed by the FDA's device clearance process.

Guidance document G91-1 specifies that proposed labeling submitted to the FDA for 510(k) clearance must address:

- **Safety and effectiveness** — (1) the population of device users, (2) each medical condition that either the labeling or advertising suggests as a use for the device, (3) relative benefits and risks, and (4) reliability. App. "C" Part II.
- **Indications for use** — (1) the medical conditions for which use is indicated, (2) the target population, (3) whether the intended use is curative, palliative, or diagnostic, and (4) special instructions for long-term use. In the indications, the FDA may require specific disclaimers of effectiveness for particular medical conditions. *Id.* Part III.
- **Contraindications** — all situations where the risk of a device outweighs any possible benefit. *Id.* Part IV.
- **Warnings** — all serious adverse reactions, potential safety hazards and limitations on use as well as steps to be taken if such a risk occurs. A warning is also "appropriate" where a common use of a device is not proven effective and is associated with a serious risk. *Id.* Part V.
- **Precautions** — (1) protective clothing, (2) special laboratory tests, or (3) any other particular procedures needed for the safe and effective use of the device. *Id.* Part VI.
- **Special patient populations** — concerns unique to users such as (1) pregnant women, (2) children, or (3) patients with anatomic or physiological limitations. *Id.* Part VII.

- **Adverse reactions** — any undesirable effects associated with use of the device, as well as steps to be taken if such an effect occurs. *Id.* Part VIII.

Guidance document G91-1 imposes additional requirements "upon prescription devices" — those the FDA does not allow to be used without a physician's prescription. *Id.* Part IX.[12] The document also details when the FDA will require that a manufacturer provide special device labeling to be given directly to lay patients. *Id.* Part XI.

The FDA's authority over labeling of 510(k) devices is so pervasive that the Agency actually rewrites the labeling proposed by device manufacturers. Appendix "D" exemplifies the extensive editorial revisions that the FDA makes to labeling submitted for 510(k) clearance.[13] The FDA's exercise of exacting control over device labeling during 510(k) review supports affirmance of the Court of Appeals' holding that all state-law tort claims attacking information contained in or omitted from medical device labeling are expressly preempted.

B. *FDA Post-Marketing Requirements Applicable To The Medtronic Device*

The FDA continues to impose requirements upon 510(k) medical devices even after they are cleared for marketing. The FDA has many post-market requirements through which it retains control over device manufacture, design, and labeling.

1. MANUFACTURING REQUIREMENTS. The FDA's extensive Good Manufacturing Practice ("GMP") regulations

12. Prescription device labeling must state its prescription-only status and include "information for use including indications, effects, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects and precautions" for all purposes for which it is advertised or represented. *Id.*

13. Expanding FDA requirements are also reflected in the time the Agency needs to act on requests to market devices. *See* 1995 Reference Guide at 15-21 (FDA pre-market approval took 262 days in 1988 and 649 days in 1994; the time for FDA action on 510(k) applications increased from 64 days to 184 days during same period).

control device manufacturing. *See* 21 U.S.C. §360j(f)(1); 21 C.F.R. Part 820. Non-compliance with GMPs "adulterates" a device. 21 U.S.C §351(h). GMPs, like the 510(k) process, are MDA "requirement[s]" that "apply to [] device[s]." *Id.* §360j(a). GMPs govern all aspects of device manufacturing and distribution, including: quality assurance, 21 C.F.R. §820.5; organization, §820.20; personnel, §820.25; buildings, §§820.40, 820.120(b); environmental control, §820.46; sanitation, §820.56; production equipment, §820.60; measurement equipment, §820.61; components, §§820.80-.81; conformity to manufacturing specifications, §§820.100-.101; reprocessing, §§820.115-.116; labeling, §820.120-.121; packaging, §820.130; storage and shipment, §820.150; installation, §820.152; inspection, §§820.160-.161; failure investigation, §820.162; complaint files, §820.198; and record keeping. §§820.180-.195. In addition, the FDA considers implanted devices such as pacemaker leads to be critical devices, 21 C.F.R. §820.3(f), and subjects them to still more GMP requirements.[14]

The GMPs are "intended to assure that. . .devices will be safe and effective." 21 C.F.R. §820.1. They are enforced by regular FDA inspections of device manufacturing facilities and records, which occur without advance notice. 21 U.S.C. §374(a,e). FDA facility inspections are thorough. *See FDA Compliance Program Guidance Manual* §7382.830, Attachment A at 8-13 (FDA May 1994) (describing scope of routine inspection). Over half of all facility inspections result in some finding of deficiency. 1 A. Levine, *FDA Enforcement Manual* ¶302 at 4 (Thompson Publishing Group May 1995).[15] An uncorrected deficiency results in FDA enforcement action against the manufacturer or its adulterated devices. 21 U.S.C. §351(h); 21 C.F.R. §820.1(a).

14. *See* 21 C.F.R. §820.81(a) (components); §820.81(b) (changes to components); §820.101 (manufacturing procedures); §820.116 (reprocessing); §820.121(a) (control numbers); §820.121(b) (proofreading of labeling); §820.151 (shipping); §820.161 (inspection); §§820.182, 820.185, 820.195 (record keeping).

15. In fiscal year 1994, FDA conducted 3,231 medical device inspections, of which 1,742 (54%) generated an "adverse" finding. *Id.*

The GMP requirements are comprehensive, and they applied to the Medtronic device. The Court of Appeals correctly held that plaintiffs' manufacturing-related claims were preempted.

2. LABELING REQUIREMENTS. The FDA exercises its power to prohibit device "misbranding" by imposing requirement[s] . . . applicable to [] device[s] under the MDA. 21 U.S.C. §360j(a) (referencing *id.* §352). The most stringent FDA labeling requirements apply to prescription-only devices, such as pacemaker leads. *See* 21 C.F.R. §§801.109(c-d); 801.15 (governing prominence). Another regulation, §801.4, defines "intended use" and delineates the uses for which §801.109 information must be included — and, conversely, excluded — on device labeling. *Id.* §801.4[16] At any time, the FDA can demand a copy of all labeling for any device. 21 C.F.R. §807.31(e).

The GMPs also impact device labeling.[17] Device manufacturers must report to the FDA in writing all incidents of the sort claimed here — where a device malfunctioned unexpectedly or contributed to serious injury or death. *Id.* §803.24. Based upon this information, FDA can take remedial action, including requiring "relabeling." *Id.* §803.3(g). The FDA can require the addition of contraindications ("do not use") or precautions ("use with caution") to device labeling. *Id.* §801.109. Should the FDA conclude that a medical device endangers public health, it has broad powers to require any labeling change that it sees fit. *Id.* §895.25(a-b).

The FDA also regulates labeling informally, particularly promotional activities by device manufacturers. Relying on *Kordel v. United States,* 335 U.S. 345, 349-50 (1948), the FDA

16. While physicians may use devices in ways other than their FDA-designated "intended use," *e.g.,* 59 Fed. Reg. 59820, 59821 (FDA Nov. 18, 1994), manufacturers may label and promote only intended uses recognized by the FDA. 21 C.F.R. §§801.4; 801.109.

17. *See* 21 C.F.R. §§820.20(a)(2), 820.120, 820.121, 820.181(d), 820.182(b). The labeling impact of GMPs is addressed in HHS Publication FDA 89-4203, *Labeling Regulatory Requirements for Medical Devices* at 17-20 (U.S. Govt. Printing Off. Aug. 1989).

expansively views its authority over "labeling" to encompass promotional activity.[18] Promotion "by or on behalf of the companies that market [medical devices] ha[s] traditionally been viewed by FDA as subject to regulation under the labeling and advertising provisions of the [FDCA]." 57 Fed. Reg. 56412, 56412 (FDA Nov. 27, 1992).[19]

The FDA's continued post-market oversight of device labeling is another ground for affirming the Court of Appeals' dismissal of plaintiffs' warning and information-based tort claims.

3. DESIGN REQUIREMENTS. An 510(k) clearance invests the FDA with ongoing control of the design of the cleared device by virtually freezing the cleared design. Any design change "that could significantly affect safety or effectiveness" requires a new 510(k) submission. 21 C.F.R. §807.81(a)(3)(i). Thus, any alternative design that plaintiffs might propose for the Medtronic pacemaker leads would, in the absence of further 510(k) clearance, be illegal under the MDA.

Minor design changes not requiring a new 510(k) are still subject to other FDA requirements. The GMPs require device manufacturers to validate or qualify all changes to device

18. Recent examples of FDA requirements imposed on promotion as "labeling" include: 57 Fed. Reg. 56412 (FDA Nov. 27, 1992) (draft policy statement regarding certain types of promotion); 59 Fed. Reg. 59820 (FDA Nov. 18, 1994) (seeking comments on draft policy statement); 60 Fed. Reg. 63384 (FDA Dec. 8, 1995) (guidelines regarding promotion). The FDA has enforced these requirements notwithstanding their ostensible "draft" status. *See, infra,* at p. 17.

19. For FDA warning letters concerning device promotion, *see* 2 W. Pines, *FDA Advertising & Promotion Manual* App. IV §C (Thompson Publishing Group 1995). These warning letters go well beyond device catalogues and brochures, and have imposed requirements upon: print and broadcast "advertising" (*id.* C-13, C-17, C-21, C-25, C-29, C-33, C-41, C-63, C-105, C-117, C-123, C-139, C-149, C-153, C-155, C-165, C-167, C-193, C-203, C-209); physician training seminars (C-3, C-39, C-53, C-67, C-89); letters to doctors (C-71, C-87, C-211); audiovisual materials (C-37, C-199); displays at medical conferences (C-85, C-135); reprints of medical literature (C-89); mail order sales literature (C-95); press releases (C-211); and even filings with the Securities and Exchange Commission (C-211).

design specifications. 21 C.F.R. §820.100(a). This requirement assures that the device being produced will continue to conform to its cleared "design specifications." 43 Fed. Reg. 31508, 31509 (FDA Jul. 21, 1978).[20]

Furthermore, design and labeling do not exist, and cannot be viewed, in isolation from one another. At any time after clearance, if a device design proves hazardous, the FDA can require addition of a warning or contraindication to the labeling. 21 C.F.R. §§803.3(g); 895.25(a-b). If the design hazard is too serious to be addressed through relabeling, the FDA can order a recall or can ban the device entirely. *See* 21 U.S.C. §§360f, 360h.

The FDA's post-market design requirements further establish that plaintiffs' design-related state-law tort claims are preempted.

C. FDA Enforcement Of Its Requirements

If it finds a medical device "adulterated" or "misbranded" for violating its requirements, the FDA has many enforcement options:

- detention without prior notice, 21 U.S.C. §334(g);
- seizure and forfeiture, *id.* §334(a)(2)(D);
- a permanent ban, *id.* §360f;
- injunctions against violations or further marketing, *id.* §332;
- felony (with proof of intent) or misdemeanor (not requiring proof of intent) criminal prosecution, *id.* §333(a);[21]

20. The FDA is now adopting "pre-production design validation," *21 U.S.C. §360j(f)(1)(A)*, requirements. *See* 58 Fed. Reg. 61952-86 (FDA Nov. 23, 1993) (describing proposed 21 C.F.R. §820.30), *mod.*, 60 Fed. Reg. 37856-58 (FDA Jul. 24, 1995). Final promulgation of §820.30 will subject the entire process of device design to formal FDA regulation.

21. In criminal cases, the Victim and Witness Protection Act also authorizes the FDA to seek a restitution order benefitting individuals harmed by a violation. *See* 18 U.S.C. §3663(a)(1).

- civil fines of up to $1,000,000, *id.* §333(f)(1)(A);
- mandatory device recall, *id.* §360h(e);
- an order requiring repair, replacement, or refund of the purchase price, *id.* §360h(b), and which may require reimbursement of third-party compliance expenses, *id.* §360h(c);
- an order requiring issuance of notice to the medical community and/or a patient safety alert, and/or a labeling change, *id.* §§352(a); 352(f)(1); 352(j); 360h(a);
- for a "minor violation," enforcement may be limited to written notice to the violator. *Id.* §336.[22]

Ongoing enforcement activity is another fertile source of FDA "requirements." For serious violations, such requirements may take the form of a court order. *See, e.g., United States v. C.R. Bard, Inc.*, 848 F. Supp. 287, 291-92 (D. Mass. 1994). Requirements are also enforced via FDA warning letters directed to both individual manufacturers and entire industries.[23] In particular, the FDA has enforced limitations on manufacturers' promotional activities even though its requirements (discussed, *supra*, at p. 15 n. 18) ostensibly remained in "draft" form. *See Washington Legal Foundation v. Kessler*, 880 F. Supp. 26, 34-35 (D.D.C. 1995) (detailing enforcement campaign).

FDA's comprehensive regulation of medical devices and the broad preemption of state law mandated by Congress are

22. For violations (minor or otherwise) discovered during FDA inspections, notice is provided by a Form 483. *See* 2 M. Heller, *Guide to Medical Device Regulation* App. IV at 7-8 (Thompson Publishing Group Oct. 1995) (sample form). For other minor violations, the violator receives a "warning letter."

23. FDA warning letters since 1990 are compiled at IHS® Regulatory Products, "The Medical Devices Library," Disc 1, *Regulation*, vol. 96-02 (CD-ROM). Absent prompt corrective action, FDA warning letters typically threaten sanctions "includ[ing], but [] not limited to injunction, seizure and/or civil penalties." *Id.*

two sides of the same coin. As Congress intended and anticipated, FDA "requirements" under the MDA go well beyond formal regulations, and all FDA "requirements" are preemptive, whether imposed by regulation, FDA guidance documents, FDA-obtained court orders, or enforcement through inspections and warning letters. 21 U.S.C. §360k(a). *See* M. Herrmann & G. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann,"* 51 Food & Drug L.J. 1, __ (1996) (forthcoming). In this case, FDA requirements pertain to every aspect of the Medtronic device challenged in plaintiffs' state-law complaint. Under the plain terms of §360k(a), all of plaintiffs' claims are expressly preempted.

III. Federal Preemption May Not Be Avoided By Basing State-Law Liability On Alleged Violations Of FDA Requirements.

Plaintiffs cannot render preemption ineffective by recasting their action as one for supposed violations of FDA requirements.[24] "[C]ompliance with the intent of Congress cannot be avoided by mere artful pleading." *Chicago and North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981). The Court of Appeals correctly stated that "preemption under the MDA cannot be defeated by a common-law suit alleging a violation of the statutory standards." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995). Plaintiffs argue (for the first time) that claims raising regulatory violations escape preemption because applicable state-law requirements are "consistent" with FDA requirements. Pl. br. at 46. Assuming that this argument has not been waived, it fails for three independent reasons. First, the terms of §360k(a) are not susceptible to an implied exception for "consistent" state requirements. To the contrary, Congress deleted precisely that exception. Second, such claims contradict the basic structure of the FDCA, under which only the federal government may prosecute violations. Third, plaintiffs' basic premise is fallacious; neither state-law standards of liability nor state-law remedies could possibly be "consistent" with FDA requirements.

24. Plaintiffs admit that their tort claims "could easily" be converted to claims for regulatory violations. Pl. br. at 46.

A. *Consistent State Requirements Are Facially Preempted By §360k(a), And Congress Deleted Language Preserving Such Claims.*

Express preemption "begin[s] with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (quoting *FMC Corp. v. Holliday*, 498 U.S. 52, 57 (1990)). Section 360k(a) "necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). It is phrased disjunctively: expressly preempting not only state requirements "different from" the FDA's requirements, but also those that are "in addition to" federal requirements — even if not "different." Had Congress intended to preserve congruent state requirements, it would have done so expressly, as it has done in many other statutes.[25]

In the MDA, precisely the opposite occurred. The scope of express preemption became broader as the MDA moved

25. *See* Poison Prevention Packaging Act, 15 U.S.C. §1476(a) (preempting state standards "not identical to the standard established under. . . this title") (emphasis added); Consumer Product Safety Act, 15 U.S.C. §2075(a) (preempting certain state requirements "unless such requirements are identical to the requirements of the Federal standard") (emphasis added); Toxic Substances Control Act, 15 U.S.C. §2617(a)(2)(B) (preempting state requirements "unless such requirement (i) is identical to the [federal] requirement") (emphasis added); Nutritional Labeling and Education Act, 21 U.S.C. §343-1(a)(1) (preempting any state standard "that is not identical to such [federal] standard") (emphasis added); Radiation Control for Health and Safety Act, 21 U.S.C. §360ss (preempting any state standard . . . applicable to the same aspect of performance of such product and which is not identical to the Federal Standard") (emphasis added); National Traffic and Motor Vehicle Safety Act, 49 U.S.C. §30103(b) ("a State or political subdivision of a State may prescribe or continue in effect a standard . . . only if the standard is identical to the standard prescribed under this chapter") (emphasis added).

through Congress. The original bills (1) limited preemption to two specified types of FDA regulations; (2) barred only state "standard[s] or regulation[s]" that "prescribe[d]. . .requirements" and "deal[t] with the same device" as the federal regulations; and (3) preserved state law where its "requirements are identical to the Federal requirements."[26] When S. 510 — the bill that eventually became the MDA — passed the Senate on April 17, 1975, it provided:

> Sec. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

94th Cong., 1st Sess. at 73-74 (1975) (emphasis added) (reproduced in Appendix "E"). *See* 121 Cong. Rec. 10688, 10709-10 (S. Apr. 17, 1975).

The preemption language now in 21 U.S.C. §360k(a) arose in the House of Representatives.[27] The House substituted that language for what was in S. 510 and passed the bill on March 9, 1976. 122 Cong. Rec. 5848 (H.R. Mar. 9, 1976). A conference committee agreed to the House amendments. *See* H. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 51 (1976) (reprinted at 1976 U.S.C.C.A.N. 1070, 1103).[28]

26. *See* H.R. 9984, 93d Cong., 1st Sess. §903(a) at 63 (1973); S. 2368, 93d Cong., 2d Sess. §903(a) at 73-74 (1974); S. 2697, 94th Cong., 1st Sess. §608(a) at 170-71 (1975). Appendix "E" reproduces the preemption provisions of all legislative precursors to the MDA between 1973 and the statute's enactment in 1976.

27. *See* H.R. 5545, 94th Cong., 1st Sess. §521(a) at 74-75 (1975); H.R. 11124, 94th Cong., 2d Sess. §521(a) at 87 (1976) (reproduced in App. "E").

28. The House preemption language passed both houses of Congress on May 13, 1976, and was signed into law on May 28, 1976. 122 Cong. Rec. 13777 (H.R. May 13, 1976); 122 Cong. Rec. 14005 (S. May 13, 1976); Pub. L. No. 94-295, 90 Stat. 539.

The explicit congressional rejection of narrow preemption in favor of the broad "different from or in addition to" language of §360k(a) defeats plaintiffs' contention that Congress silently intended to preserve "consistent" state law. To imply an exception for "consistent" state requirements would reverse the legislative process by which §360k(a) was enacted — restoring by judicial fiat the very exemption that Congress deleted from the statute. "Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." *Russello v. United States*, 464 U.S. 16, 23-24 (1983). "[W]e are mindful that Congress had before it, but failed to pass, just such a scheme. . . . We are directed by th[e] words [of the statute], and not by the discarded draft." *John Hancock Mutual Life Insurance Co. v. Harris Trust & Savings Bank*, 114 S. Ct. 517, 526 (1993) (citation omitted). *Accord Morales*, 504 U.S. at 386 n.2 ("[i]t also bears mention that the rejected Senate bill did contain language that would have produced precisely the result the dissent desires").[29]

Moreover, plaintiffs' "consistent requirements" argument meets only the "different from" prong of MDA preemption. They cannot read the alternative basis for preemption — "or in addition to" — out of §360k(a)(1). The "ordinary meaning," *Morales, supra*, of "in addition to" is neither unclear nor obscure. For example, any car owner knows that a second coat of car wax is "in addition to" the first coat although the wax is the same. The second coat takes "additional" time and effort to apply. Analogously, §360k(a)(1) precludes the "addition" of a second layer of legal scrutiny, consisting of state require-

29. The argument that only FDA regulations are preemptive meets the same fate. Where Congress meant to specify "regulations" in §360k, it did so. *See* 21 U.S.C. §360k(b) (a preemption exemption requires an FDA "regulation"). The term requirement in §360k(a) replaced less expansive language that would have preempted only a state "standard or regulation which prescribes . . . requirements." *Compare, e.g.*, H.R. 9984 §903(a) (introduced Aug. 3, 1973); S. 510 §903(a) (passed Senate Apr. 17, 1975), *with*, H.R. 11124 §521(a) (*see* App. "E"); 21 U.S.C. §360k(a).

ments "applicable" to medical devices. It eliminates duplication and prevents state courts and juries from second-guessing FDA regulatory and prosecutorial decisions. And it bars imposition of a burdensome set of overlapping requirements of the sort that Congress believed would stifle innovation by small device manufacturers.[30]

Plaintiffs also ignore §360k(a)(2). Congress broadened its scope as well — from the precursor bills' preemption only of state law "deal[ing] with the same device" to the statute's preemption of any state law that "relates to" either "safety or effectiveness" or "any other matter included in a [federal] requirement." This evolution of §360k(a) "indicat[es] that the section's pre-emptive scope was as broad as its language." *FMC*, 498 U.S. at 59 (quoting *Shaw v. Delta Air Lines*, 463 U.S. 85, 98 (1983)). "Relates to" preemption language has repeatedly been recognized by this Court as "deliberately expansive." *District of Columbia v. Greater Washington Board of Trade*, 506 U.S. 125, 129 (1992); *Morales*, 504 U.S. at 383; *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41, 46 (1987). Where all state law that "relates to" a particular topic is preempted, nothing is left, not even "consistent" state requirements:

> Nothing in [the statute] suggests that its "relating to" pre-emption is limited to inconsistent state regulation; and once again our ERISA cases have settled the matter: "The pre-emption provision . . . displace[s] all state laws that fall within its sphere, even including state laws that are consistent with ERISA's substantive requirements."

Morales, 504 U.S. at 387 (quoting *Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 829 (1988)).

Plaintiffs admit that they are basing state tort liability "by reference to [the] federal standard." Pl. br. at 45. Express pre-

30. *See, e.g., Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995), *cert. pending*, 64 U.S.L.W. 3593 (U.S. filed Feb. 16, 1996); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995).

emption of all claims "relating to" such federal standards defeats that effort. Absent the federal requirement, there can be no claim for its violation. Litigation asserting a regulatory breach necessarily "relates to" the allegedly violated requirement, and is therefore preempted. *See Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 140 (1990) (state tort claim preempted as "relating to" an ERISA plan because "there simply is no cause of action if there is no plan"). Such claims must yield to the MDA's express preemption of all state law "relat-[ing] to . . . matte:[s] included in a[n MDA] requirement." 21 U.S.C. §360k(a)(2).

Finally, an implied exemption for "consistent" state requirements would also render superfluous 21 U.S.C. §360k(b)(2)(B), which allows the FDA to preserve from pre-emption state-law requirements "compliance with [which] would not cause the device to be in violation of any applicable [federal] requirement." If identical state standards were already outside §360k(a), then the exemption in §360k(b)(2)(B) has no function. *See Morales*, 504 U.S. at 386 (rejecting narrow construction of "relates to" preemption clause that left "no purpose" to be served by an express statutory exception to preemption).

B. *Exempting "Consistent" State Requirements From Pre-emption Would Violate The Exclusive Enforcement Authority Of The FDA.*

Literal application of the broad preemption language that Congress added to §360k(a) — barring duplicative state-law enforcement of the MDA — is also consistent with the basic structure of the FDCA. *See Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 98 (1992) ("Our ultimate task in any pre-emption case is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole.") (plurality opinion). The MDA and the FDCA as a whole do not allow private rights of action, so these plaintiffs cannot act for the FDA. Only the FDA (with the Department of Justice) may enforce the FDCA and the MDA:

> all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §337(a).[31]

This Court has "assume[d]" that private plaintiffs may not seek enforcement of the FDCA. *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 810 (1986). It "would flout congressional intent" to allow either an implied private FDCA cause of action or state-law actions with FDCA violations as a "rebuttable presumption" or a "proximate cause." *Id.* at 812. Lower courts have unaniously barred private suits for violations of the FDCA or MDA.[32]

Congress tempered enforcement of the FDCA and the MDA by granting prosecutorial discretion to the FDA:

> Nothing in this chapter shall be construed as requiring the [FDA] to report for prosecution . . . minor violations of this chapter whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning.

21 U.S.C. §336. "The Act's enforcement provisions . . . commit complete discretion to [the FDA] to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). This discretion is "broad enough undoubtedly to

31. Before the FDCA was enacted, a provision granting a private right of action "for injury or death proximately caused by a violation of this Act" was deleted. S. 1944, 73d Cong., 1st Sess. §24 (1933) (reprinted in C.W. Dunn, *Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record* at 49 (G.E. Stechert 1938). *See, supra*, at p. 21.

32. *E.g., Talbott*, 63 F.3d at 30-31; *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995); *Michael*, 46 F.3d at 1329; *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 19 n.4 (1st Cir. 1994); *Rodriguez v. SK & F Co.*, 833 F.2d 8, 9 (1st Cir. 1987); *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005, 1006 (6th Cir. 1985), *aff'd on other grounds*, 478 U.S. 804 (1986); *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983); *Gelley v. Astra Pharmaceutical Products, Inc.*, 610 F.2d 558, 562-63 (8th Cir. 1979); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976).

enable [the FDA] to perform [its] duties fairly without wasting [its] efforts on what may be no more than technical infractions of law." *United States v. Sullivan*, 332 U.S. 689, 694 (1948).

If the FDA chooses to prosecute a violation, it has many enforcement tools. *See, supra*, at pp. 16-18. But under §336, the FDA also may treat a violation as "minor" and act accordingly. Indeed, this is how the FDA handles most violations, particularly of GMPs — by voluntary manufacturer compliance. *FDA Enforcement Manual* ¶403 at 6. The spectre of private tort liability would only disrupt voluntary compliance by forcing manufacturers to contest many of the FDA's thousands of findings of minor deficiencies. *See, supra*, at 13 n. 15. To exempt any tort claim asserting a regulatory violation from preemption would give minor regulatory violations a significance that neither Congress nor the FDA intended.

Even more destructive is the situation here, where plaintiffs seek to litigate supposed regulatory violations that the FDA has neither found to exist nor sought to pursue. Allowance of such claims would completely divest the FDA of its prosecutorial discretion. The Agency would lose control, not only of remedies, but even of its ability to determine whether or not there has even been a violation. If that discretion were eliminated, "the major advantages of enforcement through the Secretary would be lost," such as "expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (citation and quotation marks omitted).

The State of Florida cannot "use the threat of damages to require [a defendant] to do exactly what the [FDA] is empowered to excuse." *Chicago and NW*, 450 U.S. at 326. The MDA does not contemplate "a dual system of futile duplication of two authorities over the same subject matter." *California v. Federal Energy Regulatory Commission*, 495 U.S. 490, 502 (1990) (citation and quotation marks omitted). Preemption maintains both the FDA's exclusive enforcement authority and its prosecutorial discretion. Because §360k(a) codifies congres-

sional intent that FDA oversight be the sole avenue for adjudication of regulatory violations by medical device manufacturers, most courts of appeals have agreed with the Eleventh Circuit in this case and have held such claims preempted as little more than disguised private rights of action.[33]

As in *Chicago and NW,* only the FDA "has the power to declare [an act] unlawful" under the MDA. 450 U.S. at 324. State-law claims asserting violations of FDA requirements at best duplicate and at worst second-guess the FDA. Tort liability in this case would be a sanction (1) that the FDA has not imposed (2) for conduct the FDA has never found violative of its requirements. Such liability would be — inherently and necessarily — a state-law "requirement" that is "different from, or in addition to" the requirements enforced by the FDA under the MDA.

33. *See Talbott,* 63 F.3d at 29 ([n]othing in §360k(a) suggests that the state requirements are somehow revived by this failure to comply with the federal standard"); *Michael,* 46 F.3d at 1329 ("[u]nder the MDA, states have no authority to police. . .compliance with the FDA's procedures. . . . [I]t is for the FDA to remedy that situation using the authority Congress gave it"); *Reeves,* 44 F.3d at 307 ("[a]llowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent"); *Gile,* 22 F.3d at 544 (a plaintiff "cannot overcome a finding of preemption merely by claiming that the product was adulterated"); *Mendes,* 18 F.3d at 19 n.4 ("find[ing] nothing to support that Congress intended such a radical, unwieldy form of preemption . . . particularly where Congress did not intend to create a private right of action").

Accord, e.g., Duke v. American Medical Systems, Inc., 1995 WL 505472, slip op. at *5 (N.D. Ill. Aug. 18, 1995); *Chadwell v. Optical Radiation Corp.,* 902 F. Supp. 830, 836 (S.D. Ind. 1995); *Fender v. Medtronic, Inc.,* 887 F. Supp. 1326, 1332 (E.D. Cal. 1995); *Petix v. Kabi Pharmacia Ophthalmics, Inc.,* 884 F. Supp. 92, 99 (W.D.N.Y. 1995); *Richman v. W.L. Gore & Associates, Inc.,* 881 F. Supp. 895, 902 (S.D.N.Y. 1995); *Kemp v. Pfizer, Inc.,* 835 F. Supp. 1015, 1022 (E.D. Mich. 1993); *Scott v. Ciba Vision Corp.,* 44 Cal. Rptr. 2d 902, 911-12 (Cal. App. 1995); *Niehoff v. Surgidev Corp.,* 1995 WL 794203, slip op. at *7 (Ky. App. Nov. 17, 1995); *Mears v. Marshall,* 905 P.2d 1154, 1166-68 (Or. App. 1995); *Green v. Dolsky,* 641 A.2d 600, 606 (Pa. Super.), *appeal granted,* 652 A.2d 1324 (Pa. 1994).

C. *State-Law Non-Compliance Claims Cannot Possibly Impose Requirements Consistent With The FDA's Requirements.*

Finally, plaintiffs' facile contention that the common law of fifty states can somehow yield results "consistent" with the FDA's requirements cannot withstand analysis. Courts are "not bound by the name, description or characterization" of state law, "but will determine for [themselves] the practical impact of the law." *Hughes v. Oklahoma,* 441 U.S. 322, 336 (1979) (citation and quotation marks omitted). Common law actions would necessarily give varying and conflicting meanings to FDA requirements, particularly where, as here, the FDA has never identified and never pursued the alleged regulatory violation. The disparate judicial constructions given to 21 C.F.R. §808.1, the FDA's explication of 21 U.S.C. §360k(a), only reinforce this common-sense conclusion.[34] Those differences would multiply a thousand-fold if all FDA substantive requirements were open to competing interpretations by state-law tort litigants.

State courts and juries cannot possibly duplicate FDA interpretation and enforcement of the MDA. Every contested case would necessarily involve at least two opposing constructions of relevant FDA requirements. At least one interpretation — and quite often both (or all) of them — would not be consistent with the FDA's reading. No court or jury could unerringly pick the FDA's "correct" interpretation, even assuming that interpretation were before it. They should not be asked to undertake that impossible task.

34. *Compare Kennedy v. Collagen Corp.,* 67 F.3d 1453, 1459 (9th Cir. 1995) (§808.1 eliminates preemption of state-law tort claims), *with, Lohr,* 56 F.3d at 1345 (§808.1 allows preemption of tort claims), *with, English v. Mentor Corp.,* 67 F.3d 477, 483 (3d Cir. 1995) (§808.1 allows preemption of tort claims; if not, it would conflict with §360k(a) and be void), *cert. pending,* 64 U.S.L.W. 3469 (U.S. filed Dec. 26, 1995), *with, Duvall v. Bristol-Myers-Squibb Co.,* 65 F.3d 392, 398 (4th Cir. 1995) (§808.1 would eliminate preemption of tort claims, but conflicts with §360k(a) and is void), *cert. pending,* 64 U.S.L.W. 3439 (U.S. filed Dec. 22, 1995), *with,* 45 Fed. Reg. 67321, 67323 (FDA Oct. 10, 1980) (§808.1 allows preemption from the moment that the FDA applies a requirement to a device).

— Thus, even if state tort law were ostensibly applying the FDA's own requirements, in practice that identity could not be maintained. The parties — supported by antagonistic "regulatory experts"[35] — would dispute what the FDA's requirements are. The FDA recognizes preemption in this situation:

> In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language . . ., which may be identical to a provision in the act.

See 21 C.F.R. §808.1(d)(6)(ii) (preemption of state requirements respecting adulterated or misbranded devices"). The same reasoning bars state common law claims asserting regulatory violations. Preemption bars state law that purports to adopt FDA requirements because, in practice, disparate "interpret[ation] and enforce[ment]" *id.*, is inevitable.[36]

Available remedies are also dissimilar. Plaintiffs seek substantial damages for alleged violations the FDA has never found to exist. Not even the FDA can seek that remedy in a

35. The proof required by such litigation could well perniciously affect the FDA. At best, the Agency would be processing many litigation-inspired Freedom of Information Act requests, and retiring Agency personnel (shielded from private process during their tenure) would be subpoenaed for their knowledge of FDA regulatory activity involving any number of devices. Internal Agency disputes could become fodder for litigation, as the participants left the FDA to become highly compensated "regulatory experts" for opposing litigants. At worst, the future prospect of lucrative litigation-related employment could influence regulators' actions while still at the FDA.

36. *See* Talbott, 63 F.3d at 29:

> [W]e need only imagine how such an exception [to preemption] would operate in practice. If state tort claims were allowed to go forward, a state court would initially have to determine whether the manufacturer had complied with the MDA. . . . Under this scheme, a device manufacturer could potentially be subject to numerous inconsistent interpretations and applications of the MDA across different states, thus undermining the MDA's goal of uniformity.

civil case.[37] Money damages are both different from and in addition to the sanctions and remedies provided in the MDA and, as such, are preempted:

> We think it would . . . flout, or at least undermine, congressional intent to . . . provide remedies for violations of that federal statute [the FDCA] solely because the violation of the federal statute is said to be a rebuttable presumption or a proximate cause under state law. . . .

Merrell Dow, 478 U.S. at 812 (footnote omitted). To allow a private plaintiff a remedy for an MDA violation that is denied even to the FDA would ignore the policy choices made by Congress:

> [T]he policy choices reflected in the inclusion of certain remedies and the exclusion of others under the federal scheme would be completely undermined if [plaintiffs] were free to obtain remedies under state law that Congress rejected. . . .

Metropolitan Life Insurance Co. v. Taylor, 481 U.S. 58, 64-65 (1987) (quoting *Pilot Life,* 481 U.S. at 54).

Both the terms of 21 U.S.C. §360k(a) and its legislative history demonstrate that Congress did not intend to preserve state-law non-compliance claims from preemption. This Court should not create by implication an exception that Congress expressly deleted from §360k(a).

37. Only in criminal cases, with a higher burden of proof, can the FDA seek restitution for persons injured by violations of its requirements. *See,* supra, pp. 16-17 n. 21. Congress need not "duplicate the recovery at common law or provide a reasonable substitute remedy" when it preempts the common law. *Duke Power Co. v. Carolina Environmental Study Group, Inc.,* 438 U.S. 59, 88 (1978) (footnote omitted). *Accord Martin v. Telectronics Pacing Systems, Inc.,* 70 F.3d 39, 42 (6th Cir. 1995), *cert. pending,* 64 U.S.L.W. 3593 (U.S. filed Feb. 20, 1996).

CONCLUSION

For all of the above reasons, the judgment of the United States Court of Appeals for the Eleventh Circuit should be affirmed in part and reversed in part, with all of plaintiffs' state-law claims being dismissed as expressly preempted by the Medical Device Amendments to the Federal Food, Drug & Cosmetic Act.

Respectfully submitted,

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GUIDANCE ON THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S PREMARKET NOTIFICATION REVIEW PROGRAM
(June 30, 1986)

PURPOSE OF THE GUIDANCE

This guidance document outlines requirements for premarket notification review, and explains some points the Center for Devices and Radiological Health (CDRH) will consider when making a determination that a device is, or is not, "substantially equivalent." A consistent application of the principles set forth in the guidance should be useful to Center staff in conducting complete and expeditious reviews of 510(k) submissions.

PURPOSE OF THE PROGRAM

In brief, the premarket notification program is meant to:

- identify new devices that must be placed automatically into class III and undergo premarket approval or reclassification before they are marketed;
- classify new devices; a not substantially equivalent (NSE) new device is in class III, and a substantially equivalent (SE) new device is in the same regulatory class as the device to which it is found equivalent; and
- achieve marketing equity by allowing manufacturers of new devices that are SE to pre-Amendments devices to market their devices without facing any greater regulatory burdens than faced by manufacturers of the pre-Amendments devices.

BACKGROUND

THE STATUTE: The Medical Device Amendments were enacted on May 28, 1976. They direct FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories, class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is

placed determines the requirements that must be met before a manufacturer may distribute the device in interstate commerce.

Class I devices are subject to a comprehensive set of regulatory authorities applicable to all classes of devices, e.g., premarket notification, registration and listing, prohibitions against adulteration and misbranding, and rules for good manufacturing practices. Class II devices also need performance standards, and class III devices need premarket approval.

The Act also specifies how a new device, i.e., a post-Amendments device, is to be classified. A post-Amendments device is automatically in class III and must undergo premarket approval or reclassification before it can be marketed, unless it is within a type of device that was in commercial distribution prior to May 28, 1976 and is SE to another device within such type; or, it is within a type of device introduced after May 28, 1976 that has been reclassified into class I or II and is SE to another device within such type. A SE device is in the same class, and is subject to the same requirements, as the device to which it is SE.

Section 510(k) of the Act requires a person who wishes to introduce a device into commerce to notify the Center at least ninety days in advance. This premarket notification is referred to as a "510(k)." The Agency uses 510(k)s to determine if new devices are, or are not, SE to either a pre-Amendments device or a reclassified post-Amendments device.

CONGRESSIONAL GUIDANCE: The statutory objectives for the 510(k) program are clear. Also, the Report by the Committee on Interstate and Foreign Commerce on the Medical Device Amendments of 1976 (House Report) offers some additional guidance on program implementation, describing the term "substantial equivalence" as follows:

> The term "substantially equivalent" is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term

> should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between "new" and marketed devices in materials, design, or energy source, for example, would have a baring [*sic*] on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.[1]

If substantial equivalence were judged too narrowly, the marketing of devices that would benefit the public would be delayed; the device industry would be unnecessarily exposed to the greater burdens of premarket approval; new devices would not be properly classified; and new manufacturers of pre-Amendments type devices would not have marketing equity. If substantial equivalence were judged too broadly, the statutory purpose may not be served, i.e., devices with new uses or those presenting new or different risks would be marketed without adequate regulatory control.

THE 510(K) REGULATION: On August 23, 1977, FDA issued a final regulation for Establishment Registration and Device Listing for Manufacturers of Devices (21 CFR Part 807). Subpart E describes premarket notification procedures. The 510(k) rules were incorporated into the registration and listing regulation because the 510(k) requirements apply only to those persons required to register.

The regulation describes the circumstances under which a 510(k) must be submitted, the information required, and the FDA rules for maintaining confidentiality of submitted infor-

1. H.R. Rep. No. 94-853 pp. 36-37. The Amendments, as enacted, are comprised primarily of the bill H.R. 11124 as drafted by the Subcommittee on Health and the environment of the Committee on Interstate and Foreign Commerce and adopted by the House of Representatives. This report provides the only Congressional guidance on the criteria for substantial equivalence.

mation. Essentially, the regulation provides that a person required to register must submit a 510(k) at least ninety days before marketing a device that: (1) is being introduced into distribution for the first time by that person, or (2) is in distribution but is being significantly modified in design, or use, etc.[2]

A 510(k) must contain, among other things:

- proposed labeling sufficient to describe the device's intended use;
- a description of how the device is similar to or different from other devices of comparable type, or information about what consequences a proposed device modification may have on the device's safety and effectiveness; and
- any other information the Center needs to determine whether the device is SE

The statute provides that a new device can be SE to one of two type of devices (from hereon referred to as a "predicate device"). A predicate device is one that was in distribution prior to enactment of the Amendments, or it is a post-Amendments device that was subject to reclassification from class III to class I or II. The Center does not routinely require that manufacturers perform research to determine what specific predicate devices a [*sic*] were available in 1976, or were available at the time a post-Amendments device was reclassified from class III to class I or II; nor does the Center routinely require that all 510(k)s initially provide information on a predicate device. Instead, the Center requires submitters to provide information that compares the new device to a marketed device of similar type, regardless of whether this marketed device was marketed before or after enactment of the Amendments, or before or after a type of post-Amendments device was reclassified.

This means that the manufacturer can submit a 510(k) comparing a new device to a device that has been found to be

2. This document does not provide guidance on what changes in marketed devices are significant enough to require the submission of a 510(k), but the Center plans to issue such guidance in the near future.

SE. It does not mean, however, that the Center finds new devices SE to devices that have been found SE. It only reflects the agency's position that the similarity of a new device to a marketed device is evidence that can be considered in determining that the new device is, as is the marketed device to which it is compared, SE to a predicate device. Nevertheless, the ultimate burden of demonstrating the substantial equivalence of a new device to a predicate device remains with the 510(k) submitter, and in those occasions when the Center is unfamiliar with certain aspects of the predicate device, the submitter will be required to provide information that substantiates a claim of substantial equivalence.

The guidance that follows assumes that 510(k)s provide comparisons with marketed devices.

GENERAL POINTS CONSIDERED BY CDRH DURING THE REVIEW OF 510(K) SUBMISSIONS

CDRH normally approaches the review of 510(k)s by considering the following points:

> Does the new device have the same intended use as a predicate device? Does the new device have the same technological characteristics, i.e., same materials, design, energy source, etc.? If it has new technological characteristics, could they affect safety or effectiveness?

If the new device has a new intended use (what constitutes a new intended use is discussed below), it is considered NSE. If the new device has the same intended use as a predicate device and the same technological characteristics related to safety and effectiveness, the new device is considered SE. If the new device has the same intended use as a predicate device, and it has new technological features that could affect safety or effectiveness, additional issues are considered:

> Do the new technological features pose the same type of questions about safety or effectiveness as are posed by the predicate device with the same intended use? Are there accepted scientific methods for evaluation whether safety or effectiveness has been adversely affected as a result of the use of new technological characteristics? Is

there information to demonstrate that the new technological features have not diminished safety and effectiveness?

If the answers to any of the above questions are negative, the device is generally considered NSE.

Thus, as a matter of practice, CDRH generally considers a device to be SE to a predicate device if, in comparison to the predicate device:

- the new device has the same intended use (as discussed below); and,
- the new device has the same technological characteristics, (i.e., same materials, design, energy source, etc.); or, it has new technological characteristics that could not affect safety or effectiveness; or
- it has new technological characteristics that could affect safety or effectiveness, and
  - — it generates the same type or [*sic*] questions about safety or effectiveness:
  - — there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected as a result of the use of new technological characteristics; and
  - — there are data to demonstrate that the new technological features have not diminished safety or effectiveness.

Premarket notification submissions should be designed to answer these questions. The guidance below describes how the Center draws conclusions about the questions. The guidance covers the meaning of "intended use," technological changes that can be reviewed under the 510(k) process, data that are required in a 510(k), and what "combination" devices can be 510(k)'ed. Also, flow charts on Attachments I and II illustrate the decision making process.

THE MEANING OF INTENDED USE

While a new device must have the same intended use as a predicate device in order to be SE, the Center does not require that a new device be labeled with precise therapeutic

or diagnostic statements identical to those that appear on predicate device labeling in order for the new device to have the same intended use. Label statements may vary. Certain elements of a predicate device's labeled indication may not be critical to its intended therapeutic, diagnostic, prosthetic, surgical, etc., use. The Center's scientific expertise enables it to exercise considerable discretion in construing intended uses in the labeling and promotional materials for predicate and new devices.[3] Thus, a new device with the same intended use as a predicate device may have different specific indication statements, and, as long as these label indications do not introduce questions about safety or effectiveness different from those that were posed by the predicate device's intended use, the new device may be found SE.

For the purposes of determining whether or not the new device has the same intended use as a predicate device, the Center assesses any differences in label indications in terms of the safety and effectiveness questions they may raise. The Center considers such points as physiological purpose (e.g. removes water from blood, transports blood, cuts tissue), condition or disease to be treated or diagnosed, professional or lay use, parts of the body or types of tissue involved, frequency of use, etc. If a new device is determined to have the same intended use, the Center may then proceed to determine whether or not it is substantially equivalent. (Devices which do not have the same intended use cannot be substantially equivalent.) The following examples illustrate these concepts.

> Nonimplanted Blood Access Device: This type of pre-Amendments class II device is intended to provide access to a patient's blood so that blood can, for example, be subjected to hemodialysis. Pre-1976 devices are labeled for insertion into the femoral vein. New devices that are labeled for insertion into the subclavian vein may have the same intended use to the extent that labeling for the new and predicate devices indicates that both are

3. Ordinarily, intended use is determined by reference to "labeling" or promotional claims; only in rare cases might it be necessary to infer intended use from other types of information.

intended to provide access to a patient's blood for similar purposes. The differences in labeling described above do not undercut the fact that the new and predicate devices have the same intended use. CDRH was further able to conclude that, because the differences in labeling related only to a method of use not relevant to the effect that the insertion is to achieve (and therefore did not pose new safety or effectiveness questions) and because there were not other significant changes (in technology, design, etc.), the new device was substantially equivalent.

Conventional Dialyzer: This type of pre-Amendments device is in class II. The pre-Amendments devices are labeled for use as part of artificial kidney system for patients with renal failure. The principal purpose of the device is to remove excess water from the vascular system. Some new devices that have been found SE are labeled for use as part of a heart-lung machine to remove excess water from the vascular system at the end of surgery. Again, the Center concluded that this is not a different intended use. Differences in the labeling relate only to a nonessential condition that does not bear materially on the safe and effective use of the device, and moreover, there are no other significant changes (in technology, design, etc.); therefor, the devices are substantially equivalent.

Blood Tubing Set: This pre-Amendment class II device consists of tubing that enable blood to flow from a patient to a dialyzer and back to the patient. Some new devices that have been found SE are labeled for use in carrying blood to and from a plasmapheresis device. The Center concluded that this is not a different use for the two tubings.

The labeling differences relating to the subclavian catheter, the conventional dialyzer for use with the heart-lung machine, and the blood tubing set for plasmapheresis, are not significant enough to require a finding that the devices are for different intended uses. Moreover, the specific uses associated with the labeling modifications do not present issues of safety

and effectiveness different from those posed by the use of their predicate devices, and therefore, the devices can be found SE in terms of intended use. On the other hand, for some new devices, modifications in label indications will not be found to represent the same intended use as a predicate device, even though the intended effect of the new device is very similar to that of the predicate device. This is because slight modifications in intended use can be significant to the claimed effect or purpose of the predicate device. If a device has a different intended use, there is no reason to proceed further to decide whether the devices are substantially equivalent. (Obviously, however, some of the same issues relevant to substantial equivalence determinations may arise in assessing whether or not devices are for the same intended use, i.e., differences in labeling are judged in terms of any safety and effectiveness questions they may raise.) Two examples follow:

Long-term Percutaneous Intravasular [*sic*] Catheter: This pre-Amendments, unclassified device consists of a slender tube labeled for insertion into the vascular system for extended periods in order to sample blood, monitor blood pressure, or administer drugs. A similarly designed device has been found NSE because it is labeled for use as a spinal canal access catheter. The new device was intended to deliver drugs over an extended period of time to the spinal canal. While both devices deliver drugs into the human body, each device relates to a different body system. The concern raised by this difference led to the conclusion that the intended uses of the devices are not the same. Inserting the device into, and maintaining it in, the spinal canal raises significantly different safety issues compared to the issues posed by intravascular insertion; namely, the new device potentially posed risks to the spinal cord, whereas the predicate device did not.

Powered Aspirators: These pre-Amendments devices, currently proposed for class II, were labeled to remove loose bone chips, blood, or tissue from the body during surgery. Similarly designed new devices have been found NSE when labeled for use in "suction lipectomy." In this

new surgical procedure, the aspirating device is inserted under the skin to remove body fat, sometimes very large amounts of body fat, for cosmetic purposes. In suction lipectomy, the aspiration process performed by the device becomes the surgical procedure. It is no longer an aspirator merely used as an aid in performing another surgical procedure that is not aimed solely at the removal of fat. For these reasons, the new devices, as labeled, do not have the same intended uses as the predicate device. The difference in intended use is underscored by the fact that removal of large amounts of body fat through aspiration raises questions of safety and effectiveness not posed by the labeled use of pre-Amendments aspirators, e.g., possible metabolic changes, and permanent bagging of the skin resulting when the fat removed from the area exceed the ability of the skin to contract. Thus, the intended uses are not the same.

As the examples above illustrate, for a device to be found SE, it is important that a 510(k) for the device demonstrate that the intended use of the device does not differ from the intended use of marketed devices within the same type and that any changes in labeling are immaterial in terms of safety and effectiveness issues.

DEVICES WITH NEW TECHNOLOGICAL FEATURES

If a new device has the same intended use as a predicate device, and there are no technological differences between the new and a predicate device, the new device is SE. If the device has the same intended use and technological differences, but the technological differences could not affect safety or effectiveness, it is SE. If the device has the same intended use and technological differences that could affect safety or effectiveness, the new device may not be SE. Technological deferences may include modifications in design, materials, or energy sources; for example, changes in the power-levels of electrical surgical instruments, the use of new reagents in *in vitro* diagnostic devices, the use of new materials in orthopedic implants, and the use of new battery designs in implanted pacemakers. The Center finds devices with new technological

features to be NSE when the new feature could adversely affect safety or effectiveness in a way that is consequential under the conditions of intended use.

In taking this approach, the Center focuses on the technological differences that are medically and scientifically significant and avoids the difficulties that would arise from a mechanistic application of rigid formal criteria to the wide variety of substantial equivalence questions posed by new devices proposed for marketing under a 510(k). Substantial equivalence determinations of necessity require the Center to exercise reasonable scientific judgment. For example, the strict application of a rule that would make devices NSE if they have a new material would be inappropriate for such devices as bed pans. For other devices, a "materials rule" may seem more appropriate, e.g. for implants. Even for implants, however, such a rule would be too encompassing if applied to substitute materials known to be, or easily shown to be, equivalent or superior; for example, if applied to a new post-Amendments hip made of titanium, which is generally known to be, and can easily be shown to be, stronger and less corrosive that some stainless steel that was used in pre-Amendments hips.

Thus, from a scientific perspective, to determine which technological changes are consequential, the Center considers whether:

- The new device poses the same type of questions about safety or effectiveness as a predicate device.;
- there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected as a result of the use of new technological characteristics; and
- there are data to demonstrate that new technological characteristics have not diminished safety or effectiveness.

The examples below should help clarify these concepts.

Electrocardiographs: This device is in class II. Pre-Amendments electrocardiographs produce an analog visual display of the electrical signals produced by the

heart. Some post-Amendments devices that have been found SE display these signals in a digital, rather than analog, form.

This technological innovation could affect the effectiveness of the device, i.e., the electronic components used to produce the digital display might not achieve the accuracy of an analog display. The Center found the new devices SE because the modification presented the same question of effectiveness as posed by the predicate device, i.e., does the display accurately represent the electrical activity of the heart. Also, there are accepted bench test procedures to demonstrate comparability of accuracy between the new and predicate devices, and the necessary comparability information was presented in the 510(k).

Inflatable Penile Implant: This device is in class III. The pre-Amendments implants consist of inflatable cylinders implanted in the penis, connected a a [*sic*] reservoir filled with fluid and implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. The connections between the various parts of this system sometimes leaked. Manufacturers of post-Amendments versions of these devices modified the connector designs. These new devices have been found SE even though such a change would affect safety and effectiveness. This is because the new connectors presented the same questions of safety and effectiveness as posed by the predicate device, i.e., are the connector materials nontoxic and do the connectors leak? Since the material [*sic*] were the same, questions about the comparability of toxicity were obviated, and bench testing and clinical evidence easily and clearly demonstrated that the modified connectors were not more prone to leaks then the connectors in the predicate devices.

Perimeter: This device is proposed for classification in class I or II, depending on whether it is manually or electrically operated. The pre-Amendments devices are AC-powered or manual devices that project light on various points of a curved surface, and the patient manually indicates whether he or she sees the light. The devices are designed to determine the extent of a patient's peripheral vision. Manufacturers of post-Amendments devices have incorporated software into the device. The software automatically lights various points on the curved surface, and keeps track of whether the patient indicates that the light has been seen by recording that the patient has or has not pressed a button. The new device posed the same safety and effectiveness questions as the predicate devices, i.e., are the light-point in the appropriate places, is there risk of shock, do the points light up when they are meant to, and can the patient's reaction be accurately recorded. Because the questions are the same, and obviously accepted testing procedures can ensure comparability of performance between the new and predicate device, and because clinical data showed comparability, the new devices with a software package were found to be SE.

Hemodialyzers: This is a class II device that is used as an artificial kidney system. The device allows the removal of water and waste from the patient's blood through a semipermeable membrane. Pre-Amendments devices used cellulose based semipermeable membranes. Manufacturers of post-Amendments devices have used various other types of membrane in the filters and these devices have been found SE. This is because the new membranes raised the same questions of safety and effectiveness as the cellulose membrane, e.g., is the degree of permeability acceptable, is the material toxic, and is the degree of particulate contamination acceptable? Accepted preclinical tests, with clinical confirmation, demonstrated that the new membranes and the cellulose membranes were comparable.

On the other hand, there will be many technological changes that will make a device NSE. For example:

Heart Valves: This pre-Amendment type device is in class III. It is intended to perform the function of any of the heart's natural valves. It is constructed of prosthetic or

biological materials, or both. The Center has found many new valves to be NSE even though the new valves, in some cases, incorporated only very slight design modifications in relation to predicate valves. This is not because the device is a high risk device. Rather, it is because of the nature of the device. A minor change in design can raise questions about safety and effectiveness that are inappropriate for evaluation under 510(k). Specifically, different valve designs can lead to a different balance in the performance factors related to valves. Minor changes in a valve may make it more susceptible to fractures than its predicate, but less susceptible to occlusion. In this case, it is difficult, to compare the performance of one value to another because they present different questions about safety; each valve tends to present different risk/benefit equations. As a result, there are no accepted methods for assessing comparability. Consequently, these devices are typically found NSE.

Electrohydraulic Lithotripter: This pre-Amendments device is in class III. The pre-Amendments device was used to fragment urinary bladder stones. It consists of a high voltage cable connected to a bipolar electrode introduced into the bladder through a cystoscope. The Center found an electrohydraulic lithotripter inserted into the ureter through a cystoscope for use on ureteral stones to be SE. The principle of operation for both devices are identical. The stone is fragmented by the discharge of electricity between the two electrical poles. Another post-Amendments device, known as the Extracorporeal Shock Wave Lithotripter was NSE. This device breaks kidney stones through the use of a succession of externally generated shock waves focused on the stone. The shock waves are transmitted through water, in which the patient is sitting, and then transmitted through body tissue to the stone. The device raised questions about safety and effectiveness not present in the previous devices, e.g., the shock waves, which enter large portions of the body, could affect cardiopulmonary functions or could have had unknown effects on much of the tissue and organs in the

abdomen. An evaluation of these questions was not appropriate for a 510(k) because they presented issues outside the questions of safety and effectiveness raised by the electrohydraulic lithotripter.

Femoral stem: This lower portion of a total artificial hip replacement is a pre-Amendments device proposed for class II. Some of these devices are uncemented and are fixed by impaction of the stem into the top of the femur. The pre-Amendments impact/fit stems had smooth, straight (uncontoured) surfaces on the stem that fit into the femur. The Center found SE some post-Amendments versions of the stem that have surface variations, i.e., grooves, irregular or regular contours, etc., that allow the bone to remodel over time. The Center found to be NSE post-Amendment stems with porous coatings (for uncemented use) that require bone ingrowth into the device fixation. The contoured stem relied on impact placement and bone remodeling to an essentially smooth surface. The health of the bone would still depend upon normal bone vascularization systems even if the bone conformed to some of the slightly wavey contours. The questions of safety and effectiveness were the same as those for the traditional impact fit stem. On the other hand, for bone to grow into, and remain viable in, a porous material, the bone would need to depend upon an intricate vascularization system not normally occurring in bone that may not, in fact, develop or be sustainable. Thus, the porous coated device was found NSE because it presented new scientific questions about long term fixation.

As the examples above illustrate, for a device to be found SE, it is important that a 510(k) for the device either demonstrate that the technology of the device does not differ from the technology of marketed devices within the same type; or, to the extent that the technology does differ: explain why the device does not present new questions about safety or effectiveness, describe what accepted methods exist to test comparability of performance, and present data, generated from such tests, that demonstrate comparability. (See the 510(k) data discussion below. 510(k)s for new devices that are different from

predicate devices, but are not different from a marketed device within the same type, may not need to provide testing information.)

DATA REQUIREMENTS FOR 510(k)s

The requirements of section 510(k) of the act are intended not only to notify FDA that a device is about to be marketed but primarily to enable FDA to determine whether the device is SE to one already in commercial distribution. To fulfill this responsibility, the Center requires that a 510(k) include *descriptive data* needed to understand a new device's intended use, physical composition, method of operation, specifications, performance claims, etc. Similar information about the device to which the new device is being compared may also be required. In addition, under certain circumstances, the Center requires *performance testing information*, i.e., data from bench, animal, or clinical tests, in order to determine that a device performs according to its description.

While the Center has concluded that it should sometimes require performance testing data in order to confirm that a new device is SE, the 510(k) review process is not a substitute for premarket approval, and the Center does not attempt to address all of the issues that would be answered in a PMA in its review of 510(k)s. Data in a 510(k) should show *comparability* of a new device to a predicate device, whereas demonstration, in an absolute sense, of a device's safety and effectiveness, is reserved for PMAs.

Although there are no hard and fast rules governing all the possible data collection issues that can arise in 510(k)s, the following guidance will govern many situations.

The Center will always require descriptive data necessary to understand a new device's intended use, physical composition, method of operation, specifications, performance claims, etc. Also, the Center will always require any descriptive data necessary to understand the same characteristics of the device to which the new device is being compared.

The Center normally will not require performance testing data to substantiate equivalence if a new device does not have an important descriptive difference in comparison to marketed devices within its type i.e., it does not have a new material, method of operation, etc., and it has descriptive characteristics that are precise enough to ensure that comparability will be achieved if the new device is manufactured according to its description. For example, the Center will accept the descriptive statement that a new surgical instrument will be made of surgical grade stainless steel, as are other marketed surgical instruments, as substantiation that the new instrument is equivalent in material/composition to a predicate device. (See below for an explanation of how a comparison to any marketed device can lead to a conclusion about the substantial equivalence of a new device to a predicate device.)

The Center normally will require performance testing data to substantiate equivalence if a new device has an important descriptive difference in comparison to marketed devices within its type, and it is *not* clear from an initial review that the device has an intended use or technological change that makes it NSE; or, the new device has descriptive characteristics that are too imprecise to guarantee that comparability in performance will be achieved even if the new device is produced as described. Following is an example of when descriptive similarities are inadequate to ensure that comparability of performance will be achieved when a new device has the same descriptive characteristics as a marketed device. The fact that a new pacemaker lead and premarketed pacemaker lead are both in the polyurethane "family" does not ensure that both devices have the same chemical formulations, and differences in the chemical formulations of polyurethanes could affect safety or effectiveness. Differences in design, extrusion, and assembly of polyurethanes with the same chemical formulation could also affect safety or effectiveness. Thus, the Center would generally require performance testing information to confirm that the new lead is SE to the predicate lead.

If it is clear from an initial review that a new device has a [*sic*] intended use or technological feature that makes it NSE, the Center will not review or require performance information in the 510(k). Instead the applicant will be notified that the device is NSE, and any performance data will be reviewed in a PMA or reclassification petition.

Typically, 510(k) provides descriptive and testing data that compares the new device to another marketed device within the type, but does not necessarily compare the new device directly to a predicate device. In these cases, the Center can rely, as necessary, on performance data appearing in previously reviewed 510(k) files, in Center classification files, or in the literature, to determine that the device is not only comparable to another marketed device within its type, but is also SE to a predicate device.

Nevertheless, the ultimate burden of demonstrating the substantial equivalence of a new device to a predicate device remains with the 510(k) submitter, and in circumstances when the Center is unfamiliar with certain aspects of the predicate device, the submitter will be required to provide information that substantiates a claim of substantial equivalence.

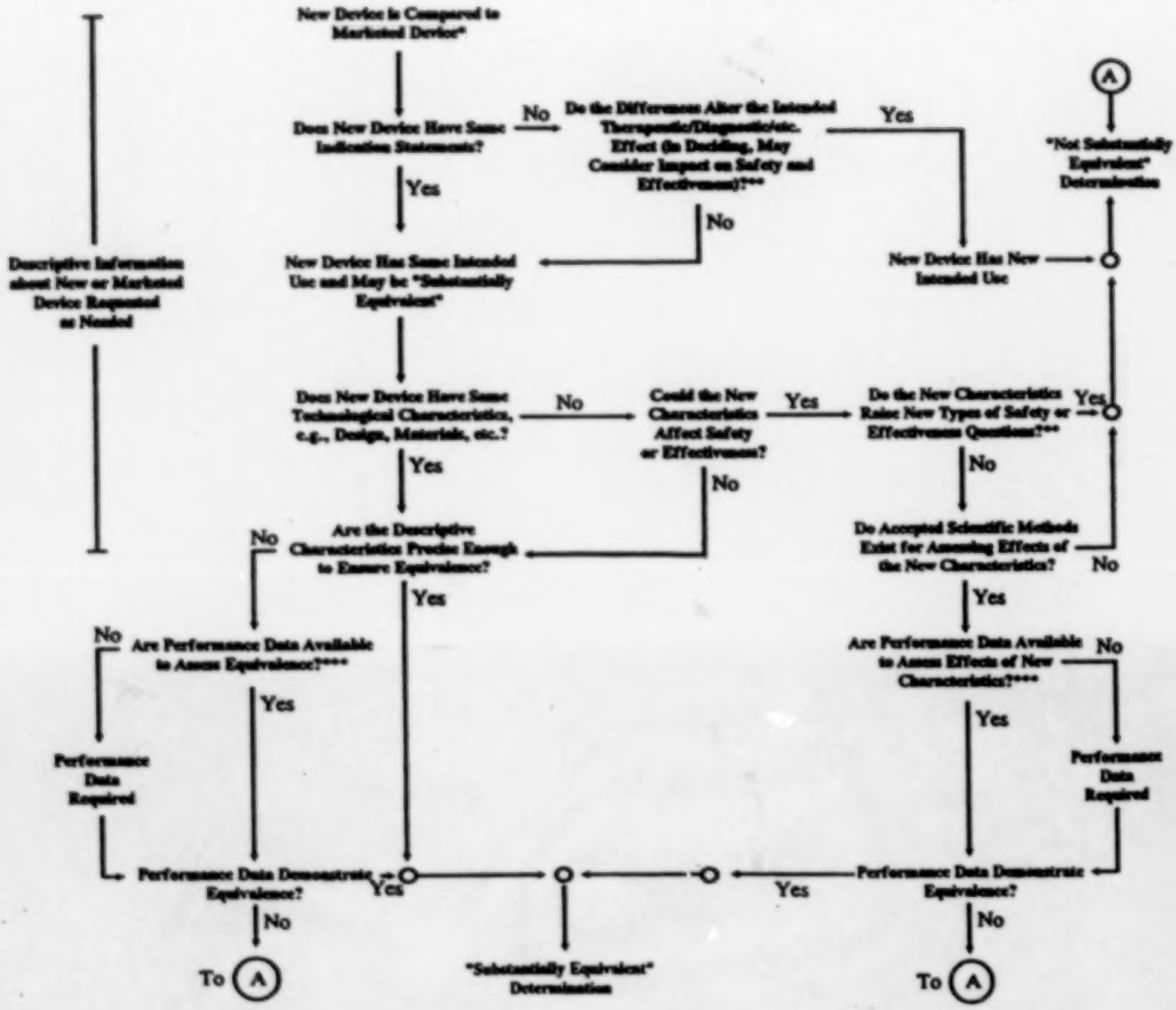
NEW DEVICES THAT ARE COMBINATIONS OF OLD DEVICES

A new device is a so-called "combination" device when it claims to have the same intended uses as two or more different types of predicate devices. Normally, this is achieved by combining two or more predicate devices into a device that is sold as a unit, e.g., a urinary catheter may incorporate a temperature measuring device; or a cardiac monitor, electrocardiograph, and blood pressure computer that were sold separately prior to May 28, 1976, might be combined into one electronic monitoring device.

When a new device combines types of devices from different classes, questions have arisen about what classification the new device will have.

In its review of the 510(k), the Center will subject the combination device to the same sorts of questions and documentation requirements that are applied to a single device. When such a device is found to be SE, it combines devices from different classes and is classified in the highest of the predicate device classifications unless the combined devices are regulatable as separate articles, e.g., they are detachable. In that case, the separately regulatable articles will be regulated in separate classes.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Memorandum

Date: MAR 8 1991 General Program Memorandum #G91-1

From: Director, Office of Device Evaluation (HFZ-400)

Subject: Device Labeling Guidance

To: ODE Review Staff

Purpose

The primary purpose of this memorandum is to formalize guidance to ODE reviewers concerning their review of labeling in device marketing submissions, especially premarket approval applications (PMAs). This guidance is intended to ensure the adequacy of, and consistency in, device labeling information. The guidance is also intended for industry use in preparing device labeling.

Background

General labeling requirements for medical devices have been established in 21 CFR Part 801. Detailed and specific labeling requirements for *in vitro* diagnostic products were promulgated under 21 CFR 809.10. Neither of these, however, provide specific definitions or explanations of some significant terms such as warnings, precautions, contraindications and adverse reactions. The lack of definitions for such terms leads to misunderstandings and disagreements between PHA applicants and the ODE review staff. Because labeling content is a key factor in the CDRH determination of whether there is reasonable assurance that a device is safe and effective for its intended use, such disputes have unnecessarily prolonged PHA review times.

Scope and Application of the Guidance

Portions of the attached "Device Labeling Guidance" that are based upon definitions and requirements in the act and applicable regulations include appropriate references thereto. Guidance on "Indications for Use," "Contraindications," "Warnings," "Precautions" and "Adverse Reactions"

paraphrase applicable provisions in the labeling requirements for prescription drugs (21 CFR Part 201). Consistency between drug and device labeling content and the terminology therein will help minimize misunderstandings by medical practitioners and patients.

While this guidance is primarily intended to ensure the adequacy of, and the consistency in, the labeling information for devices subject to premarket approval, it may also contribute to premarket notification reviews. As indicated in the "Blue Book" 510(k) Memorandum #86-3 dated June 30, 1986, a premarket notification must normally only contain proposed labeling sufficient to describe the device's intended use. Accordingly, the 510(k) decision letter finding a device to be substantially equivalent advises that this finding does not connote approval of the proposed labeling. Nevertheless, in the case of *in vitro* diagnostic devices, devices with special labeling requirements under Subpart H of 21 CFR Part 801, and devices for which the inclusion of specific directions for use, contraindications, warnings, etc. in the labeling may be critical to a finding of equivalence, the ODE premarket notification labeling review includes an evaluation of the compliance of the proposed labeling, or portions thereof, with applicable requirements under 21 CFR Parts 801 and 809, as appropriate.

This guidance was prepared by Charles H. Kyper, Assistant to the Director, Office of Device Evaluation, with input from the CDRH office of Compliance and Surveillance, Office of Health Affairs, and Office of Training and Assistance.

It should be understood that the attached guidance *is not a regulation* and that, as such, variations can occur and should be given appropriate consideration. Based upon the preceding discussion, the need for and usefulness of this guidance should be apparent. ODE reviewers are encouraged to refer to this guidance during labeling reviews and to provide it in correspondence and meetings with representatives of the device industry when appropriate. Reviewers should also keep in mind that this guidance is not intended to limit the consideration of factors that may be specific to the device when reviewing its labeling.

Effective Date: This memorandum is effective immediately.

Robert L. Sheridan

Attachment

DEVICE LABELING GUIDANCE
Table of Contents

I. Definitions
- Label
- Labeling
- Intended Uses
- Directions for Use

II. Safety and Effectiveness Considerations
III. Indications for Use
IV. Contraindications
V. Warnings
VI. Precautions
VII. Special Patient Populations
VIII. Adverse Reactions
IX. Prescription Devices
X. Restricted Devices
XI. Patient Information Labeling
XII. Disclaimer of Liability
XIII. Misbranding
XIV. Prohibited Acts

I. Definitions

Label: A "label" is a display of written, printed or graphic matter upon the immediate container of any article. [section 201(k).]

Labeling: "Labeling" includes all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [section 201(m).]

Intended Uses: The term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by their expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter,

or oral or written statements by such representatives. It may be shown by the offering or the using of the device, with the knowledge of such persons or their representatives, for a purpose for which it is neither labeled nor advertised. (21 CFR 801.4)

Directions for Use: The term "Directions for use" provides directions under which the practitioner or layman (e.g., patient or unlicensed health care provider), as appropriate, can use the device safely and for the purposes for which it is intended. Directions for use also include indications for use and appropriate contraindications, warnings, precautions and adverse reaction information. Directions for use requirements applicable to prescription and over-the-counter devices appear throughout 21 CFR Part 801 and, in the case of *in vitro* diagnostic products, under 21 CFR 809.10.

II. Safety and Effectiveness Considerations (21 CFR 860.7)

In determining the safety and effectiveness of a device for its intended use, the following factors are to be considered and addressed in the device's labeling by the inclusion of appropriate information:

- The persons for whose use the device is represented or intended;
- The conditions of use for the device, including conditions of use prescribed, recommended or suggested in the labeling or advertising of the device, and other intended conditions of use;
- The probable benefit to health from the use of the device weighed against any probable injury or illness from such use;
- The reliability of the device; and,
- Other relevant factors.

III. Indications for Use

General Statement of Indications for Use

The general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient valid scientific evidence has demonstrated that the

device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. As appropriate, the labeling should state that the device (trade name) is *"indicated"* or *"intended for use"*

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,

(2) in the relief or mitigation of symptoms associated with a disease or condition; and/or,

(3) as an aid or adjunct to a mode of therapy or diagnosis.

Additional information

When indicated or intended for use in selected subgroups of a population with a disease, symptom, or syndrome, the labeling should:

(1) describe the available evidence and state the limitations of usefulness of the device;

(2) identify specific tests needed for the selection or monitoring of the patients;

(3) if available, provide information on the approximate kind, degree and duration of improvement to be anticipated; and

(4) if relevant, include information regarding the recommended intervals between device use, the usual duration of treatment, or any modifications of such.

When safety considerations are such that the device should be reserved or restricted for use in certain situations (e.g., cases not responsive to other devices, surgical procedures or drugs), this information shall be stated.

When there are specific conditions that should be met before the device is used on a long-term basis (e.g., demonstration of responsiveness to the device in a short term trial), the labeling should identify the conditions or, if the indications for long-term use are different from those for short-term use, the labeling shall identify the specific indications for each use.

When there is a common belief that the device may be effective for a certain use or there is a common use of the

device for a condition but the preponderance of evidence related to the use or condition demonstrates that the device is ineffective, FDA may require that the labeling state that there is a lack of evidence that the device is effective for that use or condition.

IV. Contraindications

This section describes situations in which the device should not be used because *the risk of use clearly outweights* [*sic*] *any possible benefit.* Examples that may, but not always, contraindicate the use of a device include:

— Hypersensitivity to an ingredient of a permanently implanted device;

— Substantial risk of being harmed because of age, sex, concomitant therapy, disease state or other condition; or,

— Continued use in the face of an unacceptably hazardous adverse reaction.

Known hazards and not theoretical possibilities are to be listed, e.g., if hypersensitivity to an ingredient in the device has not been demonstrated, it should not be listed as a contraindication. The "Contraindications" section shall immediately follow the "Indications for Use" section of the labeling. If no contraindications are known, this section of the labeling should state "None known."

V. Warnings

Describe *serious adverse reactions* and *potential safety hazards, limitations in use* imposed by them, and *steps that should be taken* if they occur.

Include an appropriate warning if there is *reasonable evidence of an association* of a serious hazard with the use of the device. *A causal relationship need not have been proved.*

A warning is appropriate when the device is commonly used for a disease or condition for which there is a lack of valid scientific evidence of effectiveness for that disease or condition and such usage is associated with a serious risk or hazard.

VI. Precautions

Include information regarding *any special care to be exercised* by the practitioner and/or patient for the safe and effective use of the device, for example:

— Indicate or emphasize any need for proetective wear during use.

— Identify any laboratory tests or other evaluations that may be helpful in following the patient's response or in identifying adverse reactions and, if appropriate, specify the frequency of such tests or evaluations before, during and after use of the device.

The "Precautions" section of the labeling includes precautionary statements not appropriate for inclusion under other sections of the labeling. Additional guidance regarding precautions will be found in the "Special Patient Populations" section below.

VII. Special Patient Populations

Limitations on the usage of a device may be necessary for various reasons including lack of long-term safety and effectiveness data, lack of safety and effectiveness data for specific patient populations (e.g., pregnant women), growth processes still occurring in the body, and anatomical or physiological limitations on the effectiveness of the device. If the safety and effectiveness of the device for use in specific patient populations have not been established on the basis of valid scientific evidence, the "Indications for Use" section shall specifically identify the persons for whose use the device is indicated and the "Precautions" section shall include the following statement:

> "Safety and effectiveness in (e.g., pregnant women, children under the age of . . . , etc.) have not been established."

If use of the device in a certain patient population is associated with a specific hazard, the hazard shall be described in the "Precautions" section or, if appropriate, the hazard shall be stated in the "Warnings" or "Contraindications" section

and the "Precautions" section of the labeling shall refer to it, e.g., "See 'Warnings' section for information on . . . . ."

VIII. Adverse Reactions

An adverse reaction is *an undesirable effect, reasonably associated with the use of the device,* that may occur as part of the effect of the device or may be unpredictable in its occurrence.

This section includes *all* adverse reactions reasonably associated with the use of the device, including those mentioned in the "Contraindications", "Warnings" and "Precautions" sections of the labeling. The listing of the adverse reactions should be followed, if appropriate, by statements directing the reader to other sections of the labeling for additional information regarding these adverse reactions and any steps that should be taken.

Adverse reactions should be listed in descending order according to their clinical significance as determined by their severity and frequency. Provide frequency data from adequately reported clinical studies when the data is not well known to the device user (practitioner and/or patient) and/or when needed in deciding between the use of the device and an alternative procedure or approach.

IX. Prescription Devices

A prescription device is, by definition under 21 CFR 801.109, a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of the device, and hence for which "adequate directions for use" (21 CFR 801.5) cannot be prepared.

A prescription device, other than surgical instruments, is misbranded if its label does not bear:

(1) the statement, "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", or with the descriptive designation of any

other practitioners licensed by the law of the State in which that person practices to use or order the use of the device; and

(2) the method of application or use of the device.

A prescription device is misbranded if its labeling does not bear:

(1) information for use including indications, effects, routes, methods, frequency and duration of administrations, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented, with the exceptions that

(a) such information may be omitted from the dispensing package if, but only if, the directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device and the FDA Commissioner is requested to offer an opinion on a written proposal stating reasonable grounds to omit such information from the dispensing package;

(b) such information will not be required on so called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information: and

(2) the date of the issuance or the latest revision of the labeling, except for labels and cartons, that bears directions for the use of the device.

X. Restricted Device

Under the authority of section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act), the approval order for a premarket approval application (PMA) may require, as a condition of approval, that the sale, distribution and use of the device be restricted but only to the extent permitted under section 520(e) of the act. Under section 520(e) of the act, FDA may require that a device be restricted to sale, distribution and use only upon the written or oral authorization of a practitioner licensed by law to administer or use such devices (i.e., prescription device) or upon such other conditions that FDA may prescribe. Such a requirement must be based upon a determination by FDA that, because of the device's potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. If the device is restricted to use by persons with specific training or experience in its use or by persons for use in certain facilities, FDA must determine that such a restriction is required for the safe and effective use of the device. A person cannot be excluded from using a device, however, solely because that person does not have the training and experience to make him/her eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board.

When the sale, distribution and use of a device are restricted in a PMA approval order or by regulation under section 520(e) of the act, the label must include appropriate statements of the restrictions imposed by FDA (e.g., restrictions on the sale, distribution and use of the device or restrictions on the use of the device to persons with specific training or experience in its use or to persons for use in certain facilities). The label shall bear the statement, "Caution: Federal law restricts this device to sale, distribution and use by or on the order of a _____", the blank to be filled with the word "physician", "dentist", or with the descriptive designation of any other practitioners licensed by the law of the State in which that person practices to use or order the use of the device and, if applicable, followed by a descriptive phrase of the training or experience required (e.g., "trained and/or experienced in _____", the blank to be filled with, as appropriate, "the use of this device" or specified therapeutic or diagnostic procedures) and/or the facilities to which use is restricted.

In accordance with the provisions of section 502(r) of the act, advertisements and other descriptive printed material

issued by the manufacturer, packer or distributor with respect to a restricted device must include the following among other things:

(1) a true statement of the device's established name (common or usual name unless there is an official name designated by FDA or recognized in an official compendium), printed prominently and in type at least half as large as that for any trade or brand name for the device; and

(2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

Except in extraordinary circumstances, FDA cannot require prior approval of the content of any advertisement except in the case of any printed matter which FDA determines to be labeling as defined in section 201(m) of the act.

XI. Patient Information Labeling

Patient information labeling includes labeling directed to the patient as well as family members and others who administer home use devices to patients, e.g., care providers who oversee the use of infant apnea monitors and nebulizers. In determining whether patient information labeling is appropriate for a prescription device, the folloving factors, among others, should be considered:

— Should the patient be aware of alternative(s) to the use of the device if a choice is available?

— Are substantial risks or discomforts associated with the use of the device?

— Is the need for strict patient adherence to a specific treatment regimen required?

— Does substantial public or professional controversy exist about the device and its related procedures?

Patient information labeling shall include the indications for use and relevant contraindications, warnings, precautions and adverse reactions using terminology well known and understood by the average layman. Technical terms should be kept to a minimum and should be defined when necessary. If applicable, directions to ensure safe and effective use of the

device by the patient shall be included. Patient information labeling, if possible, should not exceed the seventh grade reading comprehension level.

The following sources may provide useful information regarding the information to be included as well as the terminology to be used in patient information labeling:

1. U.S.P. Dispensing Information, Volume II, Advice for the Patient®, Drug information in Lay Language
2. American Medical Association Drug Evaluations

XII. Disclaimer of Liability

Inclusion in the labeling of a disclaimer regarding the safety and effectiveness of the device for its indicated or intended use is to be avoided. Instead, labeling and promotional material may include an objective and accurate representation of the clinical experience with the device whereby the practitioner and patient are made aware not to expect a completely safe and effective outcome with the use of the device in all cases.

Inclusion of disclaimers of liability for any medical expenses or any direct or consequential damages resulting from or caused by any defect, failure or malfunction of the device will not inhibit FDA in imposing the notification and other remedies (repair, replacement or refund) provisions of section 518 of the act. The provisions of section 518 may be imposed whenever FDA determines that:

(1) The device presents an unreasonable risk of substantial harm to the public health;

(2) There are reasonable grounds to believe that the device was not properly designed and manufactured within the state of the art; or

(3) There are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than the manufacturer, importer, distributor or retailer of the device to exercise due care in the . . . use of the device.

XIII. Misbranding

Pertinent provisions in the law and implementing regulations related to medical device labeling and enforced by FDA appear below. It is important that these provisions be kept in mind both in the development of labeling by the device industry and in the labeling review by CDRH.

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) provides that a device shall be deemed misbranded if:

(1) Its labeling is false or misleading in any particular.

(2) The label does not bear the name and place of business of the manufacturer, packer or distributor and an accurate statement of the quantity of contents in terms of weight, measure or numerical count.

(3) Any required word, statement or other information to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) Labeling does not bear adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users.

(5) In the case of a restricted device, its advertising is false or misleading in any particular.

(6) In the case of a restricted device, advertisements and other descriptive printed matter (other than labeling) issued by the manufacturer, packer or distributor do not include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

In determining whether a device is misbranded because the labeling or advertising is misleading, section 201(n) of the act permits the following to be taken into account among other things:

(1) representations made or suggested by statement, word, design, device, or any conbination thereof; or

(2) the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to the consequences which may result from the use of the device to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising or under such conditions of use as are customary or usual.

Regulations applicable to medical devices provide that the inclusion of any of the following representations in device labeling constitutes misbranding of the device:

21 CFR 801.6 — False or misleading representation with respect to another device or a drug

21 CFR 807.39 — Any representation that creates an impression of official approval because of registration or possession of a registration number (e.g., inclusion of FDA establishment registration number)

21 CFR 807.97 — Any representation that creates an impression of official approval because of complying with the premarket notification regulations (e.g., inclusion of premarket notification reference number)

XIV. Prohibited Acts

Section 301(1) of the act prohibits the use in any labeling or advertising for the device of any representation or suggestion that approval of an application with respect to the device is in effect under section 515 of the act (premarket approval) or that the device complies with the provisions of section 515.

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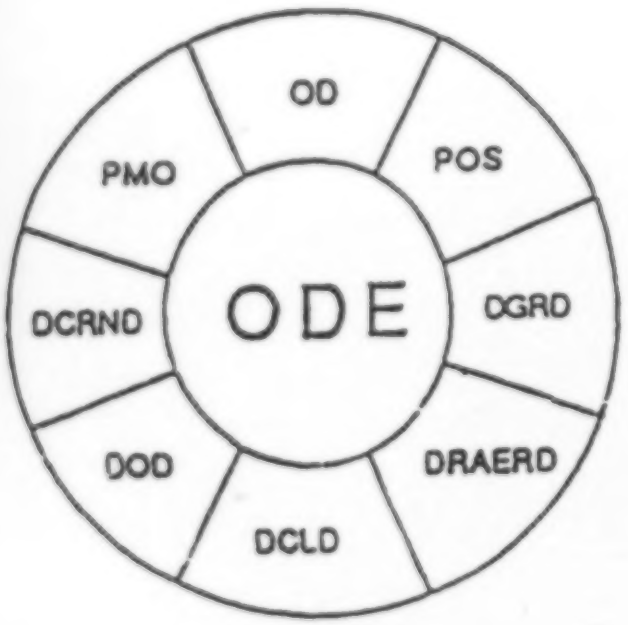
DHHS/PHS/FDA/CDRH
DIVISION OF GENERAL AND RESTORATIVE DEVICES
9200 CORPORATE BOULEVARD, HFZ-410
ROCKVILLE, MARYLAND 20850

RECEIVED
JAN 10 [illegible]



FROM: Mark N. Melkerson

DATE: 1/10/95

NO. OF PAGES:

PHONE NO: 301-594-

FAX NO: 301-594-2358

TO: Richard Trehearne, Ph.D. / Reg Affairs

FAX NO: 901-346-9738

SUBJECT: K932029

ADDITIONAL COMMENTS: Suggested Labeling Changes To Address Adequate Directions For Use, Limitations of Documented Pre Amendents Device Indications, and Potentially Misleading Claims or Statements. I Will Call You Regarding This F.
Mark

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

treatment of severe spondylolisthesis (Grade 3 and Grade 4), the specific indications ~~are as follows:~~ FOR SACRAL/ILIAC SCREW ATTACHMENT AND/OR ANTERO LATERAL SCREW ATTACHMENT ARE THE FOLLOWING:

1. Degenerative disc disease. [DEFINE CHARACTERISTICS]
2. Idiopathic scoliosis.
3. Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity.
4. Spinal fractures (acute reduction or late deformity).
5. Tumors.
6. Spondylolisthesis.
7. Stenosis.
8. Pseudoarthrosis.
9. Unsuccessful previous attempts at spinal fusion.

INSERT #1 -VE UP TO FIRST PAGE

The TSRH Spinal System, with the Variable Angle and Central Post Screws, is ~~also~~ indicated for ~~anterior~~ fixation in patients with severe spondylolisthesis (Grade 3 and Grade 4) receiving ~~fusion with~~ autogenous bone graft, ~~to be fixed or attached to the lumbar and sacral spine,~~ and to be removed after the development of a solid fusion mass.

INTO THE PEDICLES OF THE L5 VERTEBRAE AND/OR SACRAL/ILIAC ATTP
IS

NOTA BENE: The TSRH Spinal System is limited to non-cervical use. ~~Except for~~ The TSRH Staples, ~~all of the components of the TSRH Spinal System are intended for posterior spinal fixation.~~ The TSRH Variable Angle Screws and TSRH Central Post Screws, when used with the TSRH Spinal System, may also be inserted into the pedicles of the lumbar ~~spine~~ from a posterior surgical approach for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) in association with the use of autogenous bone graft, ~~otherwise their use is~~ for sacral/iliac attachment only. All of the TSRH hooks are intended for posterior thoracic and/or lumbar use only. All the CROSSLINK Plates are intended for posterior thoracic and/or lumbar use only.

ARE INTENDED FOR ANTERO LATERAL USE ONLY.
FIFTH (L5) VERTEBRAE
THE TSRH VARIABLE ANGLE AND CENTRAL POST SCREWS, WHEN USED IN POSTERIOR FIXATION ARE

ATT. IS INTE TO R REM AFTE DEVELOPI OF A SOLI FUSION

Appendix E — Preemption Provisions Contained in Precursor Legislation to the MDA

H.R. 9984 (as introduced in House of Representatives, August 3, 1973):

EFFECT ON STATE REQUIREMENTS

Sec. 903. (a) Whenever a standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the requirements of the Federal requirements.

93d Cong., 1st Sess. at 63 (1973) (never brought to vote)

S. 2368 (as passed Senate, February 1, 1974):

EFFECT ON STATE REQUIREMENTS

Sec. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

93d Cong., 2d Sess. at 73-74 (1974) (introduced Aug. 3, 1973; passed Senate Feb. 1, 1974, 120 Cong. Rec. 1783; never brought to vote in House of Representatives)

S. 510 (as passed Senate, April 17, 1975):

EFFECT ON STATE REQUIREMENTS

Sec. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

94th Cong., 1st Sess. at 73-74 (1975) (introduced Jan. 30, 1975; passed Senate Apr. 17, 1975, 121 Cong. Rec. 10688; entire text deleted by House and text of H.R. 11124 substituted; passed by House of Representatives as amended Mar. 9, 1976, 122 Cong. Rec. 5848; House-Senate Conference agreed to pertinent House amendments May 6, 1976, H.R. Rep. No. 1090, 94th Cong., 2d Sess. at 51 (reprinted at 1976 U.S.C.A.A.N. 1070, 1103); conference bill passes both House of Representatives and Senate May 13, 1976, 122 Cong. Rec. 13777 and 14005; signed into law May 28, 1976, 90 Stat. 539)

H.R. 5545 (as introduced in House of Representatives, March 26, 1975):

STATE AND LOCAL REQUIREMENTS
RESPECTING DEVICES

General Rule

Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

94th Cong., 1st Sess. at 74-75 (1975) (never brought to vote)

S. 2697 (as introduced in Senate, November 20, 1975):

EFFECT ON STATE REQUIREMENTS

Sec. 608. (a) Whenever a performance standard pursuant to section 602 or scientific review pursuant to section 603 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

94th Cong., 1st Sess. at 170-71 (1975) (never brought to vote)

H.R. 11124 (as reported by the House of Representatives, February 29, 1976):

STATE AND LOCAL REQUIREMENTS
RESPECTING DEVICES

General Rule

Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

94th Cong., 2d Sess. at 87 (1976) (introduced Dec. 11, 1975; entire text substituted for S. 510 and passed by House Mar. 9, 1976, 122 Cong. Rec. 5848; signed into law (as S. 510) May 28, 1976, Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539)

S. 510 (as enacted into law, May 28, 1976):

STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

General Rule

Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Pub. L. No. 94-295, 90 Stat. 539